EXHIBIT B

Declaration of Omar Gonzalez-Pagan in support of Motion to Exclude Expert Testimony of Dr. Paul W. Hruz *Kadel v. Folwell*, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA Case No.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.,	
Plaintiffs;) v.)	Exhibit 0001
DALE FOLWELL, in his official) capacity as State Treasurer of North)	9/29/2021 Hruz
Carolina, et al,	
Defendants.	

EXPERT WITNESS DECLARATION of PAUL W. HRUZ, M.D., Ph.D.

- 1. RETAINED AS EXPERT WITNESS VITAE: I have been retained by counsel for Defendants as an expert witness in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this declaration. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my CV is attached as Exhibit A to this declaration.
- 2. EDUCATION ACADEMIC APPOINTMENTS: I received my Doctor of Philosophy degree from the Medical College of Wisconsin in 1993. I received my Medical Degree from the Medical College of Wisconsin in 1994. I am an Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes at Washington University School of Medicine. I also have a secondary appointment as Associate Professor of Cellular Biology and Physiology in

the Division of Biology and Biological Sciences at Washington University School of Medicine. I served as chief of the Division of Pediatric Endocrinology and Diabetes at Washington University from 2012-2017. I served as the Director of the Pediatric Endocrinology Fellowship Program at Washington University from 2008-2016.

- 3. HISTORY OF BOARD CERTIFICATIONS: I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Missouri since 2000. I also have a temporary license to practice telemedicine in Illinois during the COVID-19 pandemic. My professional memberships include the American Diabetes Association, the Pediatric Endocrine Society, and the Endocrine Society.
- 4. SCIENTIFIC PUBLICATIONS IN PEER REVIEWED JOURNALS: I have published 60 scholarly articles over my academic career spanning over two decades. This includes peer-reviewed publications in the leading journals in the fields of metabolism, cardiology, HIV, and ethics including the Gastroenterology, Circulation, Diabetes, Science Signaling, the Journal of Biological Chemistry and FASEB Journal. See, my current Curriculum Vitae attached as Exhibit A.
- 5. EDITORIAL DUTIES RESEARCH GRANTS: I have served as a Reviewer for a number of leading science journals in relevant fields including the Journal of Clinical Endocrinology and Metabolism, the Journal of Biological Chemistry, Diabetes, Scientific Reports and PlosOne. I have received over 4.6 million dollars in governmental and non-governmental funding for scientific research including grants from the National Institutes of Health, the American Diabetes Association, The American Heart Association, the March of Dimes, and the Harrington Discovery Institute. I am a member of the Alpha Omega Alpha Medical Honor Society and have received the Armond J Quick Award for Excellence in Biochemistry, the Eli Lilly Award

for Outstanding Contribution to Drug Discovery, and the Julio V Santiago Distinguished Scholar in Pediatrics Award.

- 6. CLINICAL EXPERIENCE: During the more than 20 years that I have been in clinical practice, I have participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development. I was a founding member of the multidisciplinary Disorders of Sexual Development (DSD) program at Washington University. I continue to contribute to the discussion of complex cases and the advancement of research priorities in this field. In the care of these patients, I have acquired expertise in the understanding and management of associated difficulties in gender identification and gender transitioning treatment issues. I have trained and/or supervised hundreds of medical students, residents and clinical fellows in the practice of medicine.
- 7. CONSULTS-DISCUSSIONS REGARDING THE RELEVANT SCIENCE and CLINICAL ISSUES: In my role as a scientist and as the director of the Division of Pediatric Endocrinology at Washington University, I extensively studied the existing scientific research literature related to the incidence, potential etiology, and treatment of gender dysphoria as efforts were made to develop a Transgender Medicine Clinic at Saint Louis Children's Hospital. I have participated in local and national meetings where the endocrine care of children with gender dysphoria has been discussed in detail and debated in depth. I have met individually and consulted with several pediatric endocrinologists (including Dr. Norman Spack) and other professionals specializing in sexual health (including Eli Coleman) who have developed and led transgender programs in the United States. I have also consulted with, met with, and had detailed discussions with dozens of parents of children with gender dysphoria to understand the unique difficulties experienced by this patient population. I continue to evaluate the ongoing experimental

investigation of this condition. I am frequently consulted by other medical professionals to help them understand the complex medical and ethical issues related to this emerging field of medicine.

8. IN MY OPINION, A LACK OF SCIENTIFIC SUPPORT and THE ETHICAL PRINCIPLE OF INFORMED CONSENT CURRENTLY PROHIBIT MY PARTICIPATION IN "AFFIRMATION-TRANSITION" HORMONAL TREATMENTS FOR **GENDER** DYSPHORIA IN CHILDREN: Pediatric patients referred to our practice for the evaluation and treatment of gender dysphoria are cared for by an interdisciplinary team of providers that includes a psychologist and pediatric endocrinologist who have been specifically chosen for this role based upon a special interest and professional knowledge and training in this rare patient population. Due to the documented, important, ethical concerns regarding the safety, efficacy, and scientific validity of controversial, unproven, and experimental treatment paradigms, I have not personally engaged in the delivery of gender affirming medical interventions to children with gender dysphoria. Given the unproven long-term benefits and the well-documented risks and harms of "transitioning" children, I decline to participate in such experimental treatments until the science has proven that the relative risks and benefits of this approach warrant such procedures. My decision is strengthened by the knowledge that the vast majority of children who report gender dysphoria will, if left untreated, grow out of the problem — a natural coping-developmental process — and willingly accept their biological sex. Despite differences in country, culture, decade, follow-up length and method, multiple studies have come to a remarkably similar conclusion: Very few gender dysphoric children still want to transition by the time they reach adulthood. Many turn out to have been struggling with sexual orientation issues rather than Gender Discordant "transgender" identity. The exact number of children who experience realignment of gender identity with biological sex by early adult life varies by study. Estimates within the peer

reviewed published literature range from 50-98%, with most reporting desistance in approximately 85% of children prior to the widespread adoption of the "gender affirmation only" approach. Thus, desistance (i.e., the child accepting their natal, biological sex identity and declining "transitioning" treatments) is the outcome for the vast majority of affected children who are not actively encouraged to proceed with sex-discordant gender affirmation. Since there are no reliable assessment methods for identifying the small percentage of children with persisting sex-gender identity discordance from the vast majority who will accept their biological sex, and since puberty blocking treatments, hormone transition treatments, and surgical transition treatments are all known to have potentially life-long devastating, negative effects on patients, I and many colleagues view it as unethical to treat children with an unknown future by using experimental, aggressive, and intrusive gender affirming medical interventions. See, J. Cantor, Ph.D. summary of multiple research studies at http://www.sexologytoday.org/2016/01/do-trans-kids-stay-trans-when-theygrow 99.html, and other publications reviewed in detail below).

- 9. PEER-REVIEWED, PUBLISHED RESEARCH IN CREDIBLE SCIENCE-MEDICAL JOURNALS: My opinions as detailed in this declaration are based upon my knowledge and direct professional experience in the subject matters discussed. The materials that I have relied upon are the same types of materials that other experts in my field of clinical practice rely upon when forming opinions on the subject including hundreds of published, peer reviewed scientific research (and clinical) articles. A list of the most relevant articles is attached as Exhibit B to this declaration and many are cited and discussed in this report.
- 10. PREVIOUS LEGAL CASES AS AN EXPERT WITNESS: Over my career, I have provided expert medical record review and testified at deposition in less than a dozen cases. Related to the litigation of issues of sex and gender, I have been designated as an expert witness

in Joaquín Carcaño et al v. Patrick McCrory, Jane Doe v. Board of Education of the Highland School District, Ashton Whitaker v. Kenosha Unified School District, Terri Bruce v. State of South Dakota, and Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children. Only in the last case did I testify at trial. I have also served as a science consultant or subjected written testimony for court cases in Canada (B.C. Supreme Court File No. E190334) and Great Britain (Bell v Tavistock).

- 11. COMPENSATION: I am being compensated at an hourly rate for actual time devoted, at the rate of \$400 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide. I am paid in advance for all written opinions or testimony to avoid potential conflicts of interest.
- 12. BASES FOR OPINIONS My opinions documented in this report are based on my 1) knowledge, training, and clinical experience in caring for thousands of patients over many years; (2) detailed methodological reviews of hundreds of relevant peer-reviewed science publications; (3) consults, discussions, and team analyses with colleagues and other experts in the field, including attendance and participation in various professional conferences, and 4) analysis of evidence in this case including medical records, Plaintiffs' expert reports, the NC State Health Plan, legal documents (i.e. complaint, response, etc.). My investigation in this case is ongoing and I will supplement, amend or update this report as additional information becomes available for review including discovery, experts, and observations of witnesses. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on these subjects.

Evidence Reviewed: My investigation is continuing and additional evidence will be reviewed as it becomes available.

- 12A. Peer Reviewed Published Research Articles and related materials, etc. (See citations below and also attached Exhibit B).
- 12B. Relevant case documents legal complaint, response, disclosures, North Carolina Health Plan, Plaintiffs' medical records, all expert witness declarations, and other evidence as it becomes available.
 - 13. OPINIONS regarding Plaintiffs' Expert Witness Disclosures:
- The Plaintiffs' Expert Disclosures Failed to Accurately Report, Review, or Properly Α. Disclose to the Court the Dangerous Methodological Limitations, Flaws, Errors, and Defects in the Gender Transition Industry's Research Base including the Well-Known, Well-Documented International Controversies regarding the Relevant Science and Interventions (sometimes mislabeled as "treatments"). I have reviewed the expert declarations in this case from Plaintiffs' experts Drs Brown, Green, and Schechter. In my opinion, these appear to be political-ideologicaladvocate-activist opinions in support of the Gender Affirmation Medical Enterprise's ("transgender") movement and not competent, appropriate, scientific, methodological opinions. All three of Plaintiffs' experts improperly support the use of experimental, highly intrusive, and potentially harmful medical procedures despite the lack of credible, reliable, and valid scientific support for such treatments. In my opinion, their reports all failed to include a cogent, detailed, methodological discussion of the serious, ongoing, scientific, medical, and societal controversies regarding the etiology, treatment, and long-term outcomes of "gender affirmation" (sometimes mis-labeled as "transitioning") theories, methods, practices, procedures, and treatments. This omission in all three reports is quite remarkable as the scientific errors, omissions, failures, and

defective methodologies of the field of transgender medicine have produced heated controversy and garnered worldwide attention in 2020 and 2021. In the analysis that follows, I cite published analyses of Gender Transition Industry research noting significant and internationally recognized errors and defects such as low quality study designs, selective "cherry-picking" of data, and the improper misreporting of key study findings.

В. Specifically, the Plaintiffs' Expert Disclosures Failed to Accurately Report the Serious Methodological Limitations, Flaws, and Defects in the Gender Transition Industry's Methods for the Diagnostic-Labelling of "Gender Dysphoria": The Plaintiffs' expert disclosures offer misleading opinions about diagnostic systems. For example, the DSM (Diagnostic and Statistical Manual of the American Psychiatric Association) involves an often controversial consensus seeking, (not scientific evidence seeking), political-voting process that began historically as an attempt to construct a reliable dictionary for psychiatry. The DSM has historically included unreliable, since debunked, diagnoses such as "multiple personality disorder" that fueled a harmful "craze" damaging vulnerable patients until scientists, legal professionals, juries, and licensing boards put a stop to it. (See the detailed discussion below). It is important for legal professionals to understand that the DSM was created using a consensual, political process of committees and voting and does not depend upon an evidence-based, uniformly valid and reliable scientific process. Small groups of professionals, often with ideological agendas, can form committees and create "diagnoses" to be voted into the DSM. Much of DSM content is decided by the "voting" of small committees of advocates and activist practitioners whose judgment may suffer from significant financial conflicts of interest — as appears to be the case with the plaintiffs' experts in this case.

C. The Plaintiffs' Expert Disclosures Failed to Accurately Disclose and Discuss the Well-Documented Methodological Limitations, Flaws, and Defects in Gender Identity ("transgender") Subjective Clinical Assessments: The clinical assessment methodology in Sex Discordant Gender medicine is currently limited to self-report information from patients without objective scientific markers, medical tests, or scientific assessment tools. There are no reliable radiological, genetic, physical, hormonal, or biomarker tests that can establish gender identity or reliably predict treatment outcomes. A few hours of conversation with often poorly trained social workers often provides the only gatekeeping process to severe and irreversible iatrogenic surgical and hormonal injuries. Most importantly, the long-term effects of "transitioning" have never been scientifically validated. No valid-reliable methodology for such assessments has been accepted by the relevant scientific community and it appears that no known error rates for such assessments have ever been published. A more detailed discussion of the foundational science documenting the limitations and methodological defects in this field is offered below.

D. The Plaintiffs' Expert Disclosures Fail to Accurately Report Essential Methodological Problems in the Gender Transition Industry. Foundational Research including Sampling Errors, the Misreporting of Findings, the Misreporting of Relevant History, misquoting of research studies, "low quality" research designs, failures to complete randomized clinical trials, and widespread Confirmation Bias including the failure to properly explore Alternative Hypotheses (e.g., Social Contagion, Mental Illness, Complex Developmental Processes, Family Dynamics, etc.), and Other Failures of Basic Scientific Methodology: The plaintiffs' expert disclosures failed to properly discuss and disclose alternative theories/hypotheses for the rapid and nearly exponential increase of transgender cases — such as social contagion, mental illness, and/or complex developmental processes—especially as reportedly driven by news media, social media

"YouTube "influencers" (who reportedly sell "transitioning" to vulnerable youth on social media), educational systems (that reportedly pressure 1st graders to "identify as non-binary"), as well as political-activist "pro-transition" health care workers (too few of whom seem to have carefully reviewed and understood the relevant scientific history and ongoing controversies in this field).

E. The Plaintiffs 'Expert Disclosures Failed to Accurately Report Methodological and Other Problems in the Plaintiffs' Medical Records: I have also reviewed the Plaintiffs' medical records in this case. These records demonstrate many of the scientific errors, limitations, methodological errors, and informed consent errors discussed in detail below. "This includes confirmation bias, reliance on unverified patient reports, failure to consider alternative hypotheses, and failure to provide patients with the information necessary for truly informed consent."

14. TERMINOLOGY - BIOLOGICAL SEX: Biological sex is a term that specifically refers to a member of a species in relation to the member's capacity to either donate (male) or receive (female) genetic material for the purpose of reproduction. Sex thus cannot be "assigned at birth" because it is permanently determined by biology at conception. This remains the standard definition that has been accepted by the relevant scientific community and used worldwide by scientists, medical personnel, and society in general for decades. The scientific and clinical measurement of sex is done with highly reliable and valid objective methodologies. Visual medical examination of the appearance of the external genitalia is the primary methodology used by clinicians to recognize sex. In cases where genital ambiguity is present, additional testing modalities including chromosomal analysis, measurement of hormone levels, radiographic imaging of internal sexual anatomy and biological response to provocative testing are utilized.

The measurement and assessment of biological sex has been documented by valid-reliable research published in credible journals, and is accepted by the relevant scientific community. The error rate for the measurement and assessment of biological sex is very low, below 1%.

TERMINOLOGY - GENDER: Gender, a term that had traditionally been reserved for grammatical purposes, is currently used to describe the psychological and cultural characteristics of a person in relation to biological sex. Gender in such new definitions would therefore exist only in reference to subjective personal perceptions and feelings and societal expectations, but not biology. The term "gender" is currently used in a variety of ways and has thus become a controversial and unreliable term that means different things to different observers often varying according to political and ideological positions. The only definition of gender accepted by the worldwide, relevant scientific (biology, genetics, neonatology, zoology, medicine, etc.) community retains the historic biological connection to reproductive purpose with other definitions mired in controversy. The reliability and validity of various usages of the term "gender" is currently quite controversial and the relevant scientific community has accepted no use other than in relation to biological sex, which includes participate in activities related to reproduction. The serious dangers of incorrectly using the term "gender" is acknowledged by the Endocrine Society (Bhargava, A., Arnold, A. P., Bangasser, D. A., Denton, K. M., Gupta, A., Hilliard Krause, L. M., Mayer, E. A., McCarthy, M., Miller, W. L., Raznahan, A., & Verma, R. (2021). Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement. **Endocrine** bnaa034. Advance online publication. reviews. https://doi.org/10.1210/endrev/bnaa034) In addition, the error rate for multiple uses of the term "gender" outside of the accepted biologically related use is unknown, untested, and unpublished. The measurement and assessment of biological sex and gender has been documented by validreliable research published in credible journals, and is accepted by the relevant scientific community. The error rate for the measurement and assessment of biological sex and gender is very low, below 1%.

- 16. TERMINOLOGY GENDER IDENTITY: Gender identity refers to a person's individual experience and perception and unverified verbal patient reports of how they experience being male or female or a combination of these or other categories. The term "gender identity" is currently controversial. It is a term that means very different things to different observers often varying according to political, ideological, religious, and other factors. There is no current worldwide definition of "gender identity" accepted by the relevant scientific (cf. clinical) community. The reliability and validity of the term "gender identity" is controversial and not accepted by the relevant scientific community. The measurement error rate for non-biological "gender identity" is unknown, untested, and unpublished and could be very high.
- 17. TERMINOLOGY SEXUAL ORIENTATION: Sexual orientation refers to a person's enduring pattern of arousal and desire for intimacy with males, females, or both.
- 18. TERMINOLOGY DNA and CHROMOSOMES: Sex is genetically encoded at the moment of conception due to the presence of specific DNA sequences (i.e. genes) that direct the production of signals that influence the formation of the bipotential gonad to develop into either a testis or ovary. This genetic information is normally present on X and Y chromosomes. Chromosomal sex refers to the normal complement of X and Y chromosomes (i.e. normal human males have one X and one Y chromosome whereas normal human females have two X chromosomes). Genetic signals are mediated through the activation or deactivation of other genes and through programmed signaling of hormones and cellular transcription factors. The default

pattern of development in the absence of external signaling is female. The development of the male appearance (phenotype) depends upon active signaling processes.

- 19. BIOLOGICAL SEX IS BINARY NOT A CONTINUUM FOR 99%+ of MAMMALS INCLUDING HUMANS: For members of the human species (and virtually all mammals), sex is normatively aligned in a binary fashion (i.e., either male or female) in relation to biologic purpose. The presence of individuals with disorders of sexual development (along the range of the established Prader scale) does not alter this fundamental reality. Medical recognition of an individual as male or female is correctly made at birth in nearly 99.98% of cases according to external phenotypic expression of primary sexual traits (i.e., the presence of a penis for males and presence of labia and vagina for females). The recognition of an individual as male or female made at birth according to biological features has been documented by valid-reliable research published in credible journals, and is generally accepted by the relevant scientific community. The error rate for the measurement and assessment of an individual as male or female made at birth according to biological features is very low indeed, certainly below 1%.
- 20. THE GENITAL-BIOLOGICAL FUNCTION OF REPRODUCTION: Due to genetic and hormonal variation in the developing fetus, normative development of the external genitalia in any individual differs with respect to size and appearance while maintaining an ability to function with respect to biologic purpose (i.e. reproduction). Internal structures (e.g. gonad, uterus, vas deferens) normatively align in more than 99.9%+ of mammals with external genitalia, including humans. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, neonatology, developmental biology, genetics, and other relevant fields. In my opinion, all relevant sciences agree that the development of genital structures is intrinsically oriented to biological reproduction.

- 21. BIOLOGICAL ASSESSMENT OF SEX: Reliance upon external phenotypic expression of primary sexual traits is a highly accurate, reliable and valid means to assign biologic sex. In over 99.9% of cases, this designation will correlate with internal sexual traits and capacity for normal biologic sexual function. Sex is therefore not "assigned at birth" but is rather recognized at birth. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, psychiatry, neonatology, biology, genetics, gynecology, and other fields.
- 22. DISORDERS OF SEXUAL DEVELOPMENT ARE VERY RARE: Due to the complexity of the biological processes that are involved in normal sexual development, it is not surprising that a very small number of individuals are born with defects in this process (1 in 5,000 births). Defects can occur through either inherited or de *novo* mutations in genes that are involved in sexual determination or through environmental insults during critical states of sexual development. Persons who are born with such abnormalities are considered to have a disorder of sexual development (DSD). Most often, this is first detected as ambiguity in the appearance of the external genitalia. Such detection measurements are reliable and valid and accepted by the relevant scientific community. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, neonatology, gynecology, psychiatry, biology, genetics, and other fields. See, Leonard Sax (2002) How common is Intersex? A response to Anne Fausto-Sterling, The Journal of Sex Research, 39:3, 174-178, DOI: 10.1080/00224490209552139
- 23. DISORDERS OF SEXUAL DEVELOPMENT ARE NOT A THIRD SEX: Normal variation in external genital appearance (e.g. phallic size) does not alter the basic biologic nature of sex as a binary trait. "Intersex" conditions represent disorders of normal development, not a third sex. In my opinion, this view is generally accepted by the relevant scientific communities in

endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

- 24. DISORDERS OF SEXUAL DEVELOPMENT REQUIRE ASSESSMENTS OF OBJECTIVE EVIDENCE: The medical care of persons with disorders of sexual development (DSDs) is primarily directed toward identification of the etiology of the defect and treatment of any associated complications. Similar to other diseases, diagnostic tools such as the Prader scale are used to assess, measure, and assign a "stage" to the severity of the deviation from normal (e.g. assessments of objective, reliable evidence). In children with DSDs, characterization based upon phenotype alone does not reliably predict chromosomal sex nor does it necessarily correlate with potential for biological sexual function. Decisions on initial sex assignment in these very rare cases require detailed assessment of objective, reliable medical evidence by a team of expert medical providers. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.
- 25. INTERSEX CONDITIONS REQUIRE PROPER CONSIDERATION OF ALTERNATIVE HYPOTHESES AND TREATMENT PLANS: Standard medical practice in the treatment of persons with DSDs has evolved with growing understanding of the physical, psychological, and psychiatric needs and outcomes for affected individuals. Previously, it was felt that a definitive sex assignment was necessary shortly after birth with the belief that this would allow patients with a disorder of sexual development to best conform to the assigned sex and so parents-caregivers could help socialize the child to the assigned sex. Current practice is to defer sex assignment until the etiology of the disorder is determined and, if possible, a reliable prediction can be made on likely biologic and psychologic outcomes. When this cannot be done with

confidence, a presumptive sex assignment is made. Factors used in making such decisions include chromosomal sex, phenotypic appearance of the external genitalia, and parental desires. The availability of new information can, in rare circumstances, lead to sex reassignment. Decisions on whether to surgically alter the external genitalia to align with sex are generally deferred until the patient is able to provide consent. See, Lee, P. A. et al. Global Disorders of Sex Development Update since 2006: Perceptions, Approach and Care. Horm Res Paediatr 85, 158-180, doi:10.1159/000442975 (2016)). In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

- 26. METHODOLOGICAL DEFECTS of the GENDER TRANSTION INDUSTRY WHY IS THE TRANSGENDER MEDICINE FIELD STILL SO CONTROVERSIAL AFTER DECADES OF RESEARCH? :
 - A. The field of transgender medicine has long ignored basic, substantive, foundational science methodologies and ethics requirements (e.g. unverified patient reports are not a reliable basis for sterilizing vulnerable patients, unverified human memory reports are subject to contamination and misreporting, poorly designed-misreported treatment studies that show more damage than benefits are not a suitable basis for sterilizing vulnerable patients, etc.
 - B. Despite several highly defective research efforts, the Gender Transition Industry has failed to prove long term benefits that outweigh the reported harms, dangers, and serious injuries of "gender affirmation" interventions -- including inability to reach orgasm, vaginal atrophy, compromised cognitive function, lifelong reliance on medication and repeated surgical intervention to deal with the cumulative effects of these introgenic

harms, stunted growth, damage to social support systems, increased risk of serious suicide attempts, etc. In my opinion, the relevant scientific community agrees that Transgender Transition treatments are controversial, unproven, untested, and experimental – and thus not medically necessary – given the current state of scientific knowledge that exists.

- C. The Gender Transition Industry has repeatedly presented false, deceptive, and misleading information to the public and to patients regarding the known risks, dangers, injuries and benefits of "affirmation treatments". (E.g. the Branstrom, Turban, and related research errors of omission and misreporting.)
- D. Without competent, valid, peer reviewed published research support; the Gender Transition Industry relies upon support from "professional associations". Yet such associations are engaged in consensus-seeking-political voting methodologies and not evidence-based, peer reviewed science. Such political-professional associations have made similar, disastrous mistakes in the past. For example, the American Medical Association supported racist, "junk" science eugenics "treatments" in the 1930s and the American Psychiatric Association did not act to prevent or halt the harms of the repressed-memory/multiple personality industry of the 1990s.
- E. As a result of these many defects of methodology and ethics, the Gender Transition Industry and its "treatments" are not generally accepted by the relevant scientific community.
- F. As a result of these many defects of methodology and ethics, the Gender Transition Industry's assessments and "treatments" have no known nor published error rate.

- G. A key investigative hypothesis is whether the Gender Transition Industry is simply the latest harmful "junk science" fad and consumer fraud in the medical-psychiatric industry following the misadventures of lobotomies, recovered memory therapy, multiple personality disorder, rebirthing therapy, and others.
- H. National science reviews in England, Sweden, Finland and by the Cochrane Review have all uncovered serious methodological and ethical failures in the Gender Transition Industry thus supporting the alternative investigative hypothesis that the Gender Transition Industry is engaged in a form of hazardous consumer fraud resulting in harm to many vulnerable patients. (E.g., In Expósito-Campos P. A Typology of Gender Detransition and Its Implications for Healthcare Providers. J Sex Marital Ther. 2021;47(3):270-280. doi: 10.1080/0092623X.2020.1869126. Epub 2021 Jan 10. PMID: 33427094, the authors claim to have identified 60,000 case reports of detransitioners world-wide on the Internet.)
- 27. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY-LIMITATIONS and HAZARDS OF RELYING ON UNVERIFIED PATIENT SELF-REPORT DATA WITH NO OBJECTIVE EVIDENCE: IN CONTRAST TO DISORDERS OF SEXUAL DEVELOPMENT, GENDER DYSPHORIA CANNOT BE RELIABLY, OBJECTIVELY ASSESSED AS IT IS BASED ON PATIENT SELF-REPORTS (no blood tests, no x-rays, no lab results, no objective data): Individuals who verbally report experiencing significant distress due to perceived discordance between gender identity and sex cannot currently be reliably, validly, and objectively assessed as experiencing "gender dysphoria". (See, American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed, (2013). Although gender perceptions, feelings, and "identity" usually align with biological sex, some individuals

report experiencing discordance in these distinct traits. Specifically, for example, biologic females may report experiencing that they identify as males and biologic males may report experiencing that they identify as females. As gender by definition is distinct from biological sex, one's gender identity does not change a person's biological sex. There is currently no known reliable and valid methodology for assessing the accuracy or nature of unverified, verbal reports of discordant "identity". There is thus no known "error rate" for relying upon such reports to engage in hormonal and surgical treatments that might result in lasting, irreversible damages to normal, healthy organs and the destruction of normal biological functions (e.g. sterility) as the current research documents. In my opinion, my view is generally accepted by the relevant scientific communities in endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

28. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA UNRELIABLY ASSESSED BY HEALTH CARE PROFESSIONALS -- THE RELEVANT SCIENCE DOCUMENTS THAT MENTAL HEALTH CARE PROFESSIONALS ARE UNRELIABLE HUMAN "LIE DETECTORS" ("often no better than flipping a coin"): Currently, there is no known methodology for reliably discerning true from false patient reports without corroborating evidence such as radiology, lab tests, or other objective evidence. The Gender Transition Industry's sole reliance upon patient self-report data carries unknown risks of errors, misinformation, deception and lasting harm to patients from treatments that deliberately damage healthy organs and destroy essential normal bodily processes thus often producing sterility. Assessment of gender dysphoria currently depends almost entirely upon unverified, self-

reported evidence provided by patients. A patient's spoken or written reports of alleged "memories" of symptoms and behaviors are the only source of evidence for the diagnosis in many cases. This is a source of potentially profound unreliability in patient care as the relevant science documents that physicians are poor "lie detectors" — often no more reliable in discerning false reports than flipping a coin — and sometimes much worse. The relevant research also documents that even though humans (including therapists) are poor "lie detectors" many poorly trained physicians and mental health professionals personally – and falsely -- believe they are "experts" at this complex and difficult task. See, e.g., Vrij, Aldert, Granhag, P. and Porter, S. (2010) Pitfalls and opportunities in nonverbal and verbal lie detection. Psychological Science In The Public Interest, 11 (3). pp. 89-121. ISSN 1529-1006 10.1177/1529100610390861. "The final error that I will highlight is that professional lie catchers tend to overestimate their ability to detect deceit. Research has consistently shown that when professional lie catchers and laypersons are compared, "professionals are more confident in their veracity judgments but are NO more accurate". Emphasis added. See also, Rosen, G. M. and Phillips, W.R., A Cautionary Lesson from Simulated Patients, Journal of the American Academy of Psychiatry and Law, 32, 132-133, (2004).

29. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA UNRELIABLY ASSESSED BY HEALTH CARE PROFESSIONALS --SOCIAL MEDIA "INFLUENCERS" ARE REPORTEDLY TRAINING PATIENTS TO **FABRICATE SYMPTOMS** TO **GAIN RAPID ACCESS** TO "TRANSITION" INTERVENTIONS. Because Mental Health Professionals and Physicians are not capable of reliably discerning true from false patient reports, nobody knows how many Gender Dysphoria

patients have been coached-trained to deceive providers to gain easier and more rapid access to hormones/surgery: An important methodological error of the gender transition industry is the reliance on patient self-reports alone — and the lack of objective corroborative evidence (no xrays, no blood tests, no genetic tests, no MRI's, etc) — to engage in experimental "treatments" causing sterility and other long-term harms. One potential hazard of this limited, unreliable selfreport methodology can be seen in the recently reported increase of "rapid onset gender dysphoria" ROGD in adolescent females. For decades, the large majority of GD patients were early onset males. In contrast, in just the past 5 years, the majority of new GD patients are female patients with no long-term GD history. Many of the "rapid onset" adolescent patients' parents have reported a very rapid onset of GD symptoms linked to peer or school pressures or YouTube "training"—thus coming out as "trans" in groups of friends or following school "gender training" programs. At the same time, there have been reports of YouTube "Trans Influencers" whose "video blogs" are watched by millions as they provide detailed coaching to their adolescent girl followers on how to "lie to medical providers to obtain easier access to TG hormone and surgical The reliance upon unverified self-report data –an unreliable diagnostic treatments rapidly". methodology -- may well be one source of the ongoing and internationally reported failure of research on Gender Transition Industry interventions (sometimes mislabeled as "treatments) to provide consistent, reliable and valid evidence of long term benefits that would offset the welldocumented long-term harms, injuries, and damages (e.g. sterility, stunted growth, bone loss, etc) produced by this burgeoning medical industry.

30. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA UNRELIABLY ASSESSED BY MENTAL HEALTH PROFESSIONALS --

THE SCIENCE OF MEMORY SHOWS THAT UNVERIFIED PATIENT "MEMORY" REPORTS COULD BE QUITE INACCURATE THUS PRODUCING ADDITIONAL RISKS OF UNRELIABLE DIAGNOSIS AND HARMFUL INTERVENTIONS: Decades of scientific research studies have shown that human memory reports — often the sole source of evidence for providers to engage a Gender Dysphoria patient in hazardous, experimental "gender transition" treatments — are subject to manipulation, implantation, contamination by post-event sources, source amnesia, and other errors. As world memory expert Prof. Elizabeth Loftus has noted, "False memories, once created — either through misinformation or though suggestive processes — can be experienced with a great deal of emotion, a great deal of confidence and a lot of detail, even though they're false." See Loftus, E. F. (2002) Memory Faults and Fixes. Issues in Science & Technology, National Academies of Science, 18, # 4, pp 41-50 See, also, e.g., Loftus, E. F. (2005) Planting misinformation in the human mind: A 30-year investigation of the malleability of memory. Learning and Memory, 12, 361-366.

31. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the reliance upon often science-illiterate mental health professionals to assess unverified patient reports -- ALTHOUGH MUCH OF MEDICINE BECAME SCIENCE-BASED IN THE 20th CENTURY — THE MENTAL HEALTH FIELDS REPORTEDLY CONTINUES TO LAG BEHIND:

The Gender Transition Industry often involves social workers or other mental health professionals "assessing" patients reporting Gender Dysphoria to determine if they will benefit from "affirmation" medical interventions. Given the extraordinary lack of competent, methodologically sound research (See, reviews by England, Sweden, Finland, the Cochrane review and others below) justifying the use of gender affirmation "treatments" there is no method for

mental health professionals to reliably determine who might benefit from experimental interventions. Such unreliable assessment protocols risk harm to patients as they depend upon the widespread unreliable method of having psychotherapists depend upon "clinical judgment" methodologies to make life-changing decisions and offer "professional" opinions with little or no scientific validity. See, e.g., Mischel, W. Connecting Clinical Practice to Scientific Progress, Psychological Science in the Public Interest, November 2008, vol 9, no 2 i-ii. The past President of the Association for Psychological Science, Prof. Walter Mischel, stated "the current disconnect between psychological science and clinical practice is an unconscionable embarrassment". See, Mischel, W. Connecting Clinical Practice to Scientific Progress, Psychological Science in the Public Interest, Vol 9, No 2, 2009.

Over the past century many components of the health care system — surgery, radiology, laboratory testing, internal medicine, pharmacological systems, etc. — became science-driven and far more effective and reliable. Courts are often unaware that this transformation — moving from widespread use of unreliable methodologies ("junk science") to the widespread use of reliable science-based methodologies — has, in many ways, not yet occurred in the mental health system. See, e.g., West, Catherine, 'An Unconscionable Embarrassment', Association for Psychological Science, Observer, October 2009, See, http://www.psychologicalscience.org/index.php/publications/observer/2009/october-09/anunconscionable-embarrassment.html; See, also Baker, T., McFall, R. & Shoham, V., Current Status and Future Prospects of Clinical Psychology: Toward a Scientifically Principled Approach to Mental and Behavioral Health Care, Psychological Science in the Public Interest, Vol. 9, No. 2 (2009); see also, Harrington, A., Mind Fixers: Psychiatry's Troubled Search for the Biology of Mental Illness, W. W. Norton & Company; 1st edition, April 16, 2019; See also, Dawes, R.M.,

House of cards: Psychology and psychotherapy built on myth, New York: Free Press (1997); See also, Garb, H. N., & Boyle, P. A (2003). Understanding why some (mental health) clinicians use pseudoscientific methods: Findings from research on clinical judgment. In S. O. Lilienfeld, S. J. Lynn, &. J. M. Lohr (Eds.), Science and pseudo-science in clinical psychology (pp. 17–38). New. York, NY: Guilford Press.

- METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY 32. include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA ASSESSED BY MENTAL HEALTH PROFESSIONALS: DYSPHORIC REPORTS ARE COMMON FROM CHILDREN WITH A RANGE OF ILLNESSES: Reports of feelings of anxiety, depression, isolation, frustration, and embarrassment are not unique to children with gender dysphoria, but rather are common to children who differ physically or psychologically from their peers. Difficulties are accentuated as children progress through the normal stages of neuro-cognitive and social development. In my clinical practice of pediatric endocrinology, this is most commonly seen in children with diabetes. Attempts to deny or conceal the presence of disease rather than openly acknowledge and address specific needs can have devastating consequences including death. With proper acknowledgment of the similarity and differences between children with gender dysphoria and other developmental challenges, prior medical experience in treating a range of reported troubles can guide the development of effective approaches to both alleviate suffering and minimize harm to school aged and adolescent children experiencing gender dysphoria.
- 33. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA ASSESED BY MENTAL HEALTH PROFESSIONALS -- COURTS SHOULD

BE AWARE THAT CLINICAL EXPERIENCE IN THE MENTAL HEALTH FIELDS - WHERE CLINICIANS OFTEN LACK ACCURATE FEEDBACK — IS OFTEN OF LIMITED VALUE .

As the Gender Transition Industry routinely permits poorly qualified social workers or other mental health professionals to subjectively make life changing decisions in Gender Dysphoria cases — such mental health professionals often unreliably overestimate their ability to offer such "crystal ball" assessments and predictions. Few of these professionals seem aware of the research showing the grave limitations on the experience, judgment, and methodologies of mental health professionals. See, e.g., Tracey, T.J., Wampold, B.E., Lichtenberg, J.W., Goodyear, R. K., (2014) Expertise in Psychotherapy: An Elusive Goal, American Psychologist, Vol. 69, No. 3, 218-229. "In a review of expertise across professions, Shanteau (1992) identified several professions in which practitioners develop expertise, which he defined as increased quality of performance that is gained with additional experience. These professions, which demonstrate there can be a relation between experience and skill, include astronomers, test pilots, chess masters, mathematicians, accountants, and insurance analysts. Shanteau also identified several professions for which experiential expertise was not demonstrated, including [mental health professionals]. He attributed the differences between the two types of professions to the predictability of their outcomes and the unavailability of quality feedback." For example, airline pilots, or even more clearly Navy fighter pilots who land on aircraft carriers practice their professions in full view of hundreds of people. If they err, people die. If they are, off course, unstable, or inaccurate in their performance, immediate consequences, retraining or loss of profession is the immediate outcome. In contrast, a social worker, psychologist, or psychiatrist, sitting alone in a room with a troubled patient can make erroneous statements, use unreliable methodologies (e.g., naively believing whatever patients tell them or believing that they are "professional human lie detectors"), believe false and misleading notions about human memory, demonstrate ignorance of the serious defects in transgender treatment research, and fail to properly inform patients of the risks and benefits of treatments, etc. Mental health professionals can make such egregious errors for decades without receiving timely, accurate feedback. Without accurate feedback there is a failure of the learning process and improvements are difficult or not possible. Such limiting processes can continue for many years of practice. This is why mental health professions have been listed as doing the type of work that often does not lead to improvements in "clinical experience"— even over many years of practice. Gender discordant ("transgender") patients are rarely, if ever, informed of these limitations on mental health professionals' knowledge, training, or experience nor the limitations of mental health "assessments" based on unverified self-reported "memory" data.

34. HISTORICALLY, THE MEDICAL and SOCIAL SCIENCES HAVE AT TIMES BEEN IMPROPERLY TAINTED BY POLITICAL IDEOLOGIES. IT IS IMPORTANT FOR LEGAL PROFESSIONALS — ESPECIALLY JUDGES —TO UNDERSTAND THE ESSENTIAL DIFFERENCES BETWEEN METHODOLOGICALLY COMPETENT, TESTABLE-TESTED-RELIABLE-VALID PEER REVIEWED SCIENCE v. the CONSENSUSSEEKING, VOTING PROCESSES OF POLITICAL-PROFESSIONAL ASSOCIATIONS and RELATED ORGANIZATIONS:

Professional Association voting processes are not a reliable nor valid scientific methodology. Professional, political, or other association consensus-seeking voting processes and procedures are neither reliable nor valid, nor tested and proven scientific methodologies. They are votes taken by committees - too often small committees of activists and ideologues with inadequate methodological training. Such non-scientific voting processes and procedures have never been

accepted as reliable and valid scientific methods by the relevant scientific community. Such voting processes and procedures have no known error rate. Historically, it should be noted that "professional associations" have a tainted history of supporting unproven, controversial notions that were later proven to be improper, unreliable, and/or unethical.

A. The American Medical Association (AMA): As an example of professional association support of controversial ideologies, AMA supported eugenic proposals to "improve the quality of the human stock" by coercive *sterilization* of "defective and undesirable Americans" and selective breeding. During the 1890's the renowned surgeon Albert Ochsner was invited to speak about his vasectomy procedure to the meetings of the American Medical Association. Dr. Ochsner recommended surgical vasectomies to prevent the reproduction of "criminals, chronic inebriates, imbeciles, perverts, and paupers." (See, Oshsner, AJ, Surgical treatment of habitual criminals. JAMA, 1899:32:867-868).

The controversial support of the AMA for such racist, eugenics ideologically-tainted pseudoscientific notion was a political and not a scientific process. Similarly, the American Breeders Association founded an Eugenics Record Office with an advisory board that included a Harvard physiologist, a Princeton psychiatrist, a University of Chicago economist, and Alexis Carrel of the Rockefeller Institute for Medical Research, a recipient of the Nobel Prize in Medicine. This movement was focused on "terminating the bloodlines" of the "submerged lower ten percent of the population with 'defective germ-plasm'". (See, Black, E. War Against the Weak, New York, NY, 2003).

With the support of professional associations like the AMA, a Model Eugenics Sterilization Law was proposed to authorize sterilization of the "socially inadequate", that is, those supported in institutions or maintained at public expense. The model law encompassed the "feebleminded, insane, criminalistic, epileptic, inebriate, diseased, blind, deaf, deformed, and dependent"—including "orphans, ne'er-do-wells, tramps, the homeless and paupers". Eighteen states passed laws based on the 1922 model legislation and sixty-four thousand people were forcibly sterilized. Supporters included Margaret Sanger who in her 1932 essay "My Way to Peace" proposed that "the whole dysgenic population would have its choice of segregation or *sterilization*" (Sanger, M., My Way To Peace, Birth Control Review, Jan 17, 1932; Singleton, M.M. The 'Science 'of Eugenics: America's Moral Detour, Journal of American Physicians and Surgeons, Vol 19, No 4, Winter 2014.)

A key lesson from this tragic era is that the non-scientific, consensus-seeking voting processes of "associations" can produce danger to the public and patients. Although directed by persons who know or should know how to conduct proper scientific methods, association voting methods are politically-ideologically tainted processes — and not based upon valid-reliable, methodologically-competent science. Again, such professional "associations" operate via consensus-seeking and ideology and not evidence-seeking scientific methodologies. Such professional organizations make decisions by voting and not by conducting ethical, scientifically valid, methodologically reliable, peer reviewed and published science with known error rates.

B. The World Professional Association for Transgender Health (WPATH), The American Academy of Pediatrics (AAP), and the Endocrine Society: This methodological critique and history of association errors and misadventures is quite informative when assessing the "professional association" consensus seeking methodologies including voting and political activities such as those of WPATH, the AAP, the American Endocrine Society and similar groups as they adopt support for the "politically correct" but scientifically defective, ideologically driven Gender Transition Industry. Consensus seeking (voting) methods are not scientific evidence-based

methodologies. Courts should take case not to be deceived by the "positions" of Associations – no matter how large or vocal. The net effect of many the Gender Transition Industry's methods and procedures is the sterilization of tens of thousands of children, adolescents, and adults. This is a sobering reminder of previous, now infamous, medical misadventures. (See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36; See also, McHugh, P., Psychiatric Misadventures, The American Scholar, Vol. 62, No. 2 (Spring 1993), pp. 316-320;

C. The Diagnostic and Statistical Manual of the American Psychiatric Association (DSM):

A final example of the methodological limitations of relying upon "association voting" methods is the Diagnostic and Statistical Manual of the American Psychiatric Association. The DSM (and also the International Classification of Diseases- ICD) system(s) have confused some courts in the past. Simply put, reliability data, validity methodological analyses, and error rates are not supplied nor supported by the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM).

Today's American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (Version 5) employs the term "Gender Dysphoria" and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other. It is important to reiterate that the DSM is not a reliable-valid scientific journal publication. The DSM began as an attempt to create a dictionary for psychiatry. The process by which DSM classifications are created involves voting by committee — this is not a reliable-valid scientific process. The committees' recommendations are approved or rejected by superordinate committees. DSM content is largely decided by consensus-seeking methodologies — such as "voting" by small committees of advocates and activist practitioners whose judgment may suffer from significant

financial conflicts of interest — as appears to be the case with all three of the Plaintiffs' experts in this case. The limitations of the DSM methodology are well known in the relevant scientific community. In my opinion, these views are generally accepted by the relevant scientific community.

The DSM has become increasingly controversial in recent years – including being "dumped" by the National Institute of Mental Health as a key basis for research funding. See, Lee, C., The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA. Psychology Today News Blog at https://www.psychologytoday.com/us/blog/sideeffects/201305/the-nimh-withdraws-support-dsm-5 ["Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is withdrawing support for the APA's manual. In a humiliating blow to the American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency ... would be "re-orienting its research away from DSM categories."] See also. https://www.nimh.nih.gov/about/directors/thomas-insel/blog/2013/transformingdiagnosis.shtml "Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure. In the rest of medicine, this would be equivalent to creating diagnostic systems based on the nature of chest pain or the quality of fever. Indeed, symptom-based diagnosis, once common in other areas of medicine, has been largely replaced in the past half century as we have understood that symptoms alone rarely indicate the best choice of treatment. Patients with mental disorders deserve better. NIMH has launched the Research Domain Criteria (RDoC) project to transform diagnosis by incorporating genetics, imaging, cognitive science, and other levels of information to lay the foundation for a new classification system."]

In sum, professional association "positions" are not based upon competent, credible, reliable and valid scientific methodologies. Professional association "positions" on gender affirmation assessments and treatments remain very socially, medically, and scientifically controversial – and increasingly so. The association "positions"—since they are produced by voting and not methodologically reliable-valid evidence -- have not been generally accepted by the relevant scientific community and they have no known, nor published, error rates.

35. MEDICINE and SOCIAL SCIENCE HAVE AT TIMES BEEN TRAGICALLY TAINTED AND THOUSANDS OF PATIENTS DAMAGED BY RELIANCE ON METHODOLOGICALLY DEFECTIVE PATIENT SELF-REPORTS and ANECDOTAL EVIDENCE:

Case histories, case reports, and verbal patient reports-statements and medical records of individual patients are all helpful sources of information and at times essential to the proper treatment of individual patients. Such information has often proven helpful in generating testable hypotheses for scientific research. Such self-report and anecdotal information, however, can contain errors, distorted memories, misinterpretations, delusions, confusions, manipulations, and other kinds of errors. In sum, case histories, case reports, and the statements and medical records of individual patients are anecdotal case histories or patient reports (stories of often unknown reliability). Such evidence is not sufficient for reliable, valid, tested, proven, peer reviewed scientific methodologies. Case histories, case reports, and the statements and medical records of individual patients have never been accepted by the relevant scientific community as reliable, valid, peer-reviewed published scientific research. Such case histories, case reports, and the statements and medical records of individual patients have no known error rates with some care

reports being highly accurate documentation of objective evidence and others being filled with highly subjective, uncorroborated, unverified verbal reports of patient emotional states.

An example of disastrous medical misdirection from anecdotal patient reports is the Repressed Memory Therapy (RMT) movement of the late 1980s and 1990s. This explosive epidemic of "recovered memories" and "multiple personality disorder" (MPD) patients led to the rapid creation of "specialty clinics" and hospital units throughout the nation as tens of thousands of new RMT and MPD patients accused parents of horrific crimes.

The intense furor resulted in the FBI investigating hundreds of anecdotal crime reports from psychotherapy patients. After years of investigations, Kenneth Lanning, the Director of the FBI Behavioral Unit, reported the lack of corroborative evidence for the patient allegations following "recovered memory therapy". He suggested that "therapists needed to explain" why so many therapy patients came to adopt, fervently believe in, and report radically transformed, terrifying alterations to their own biographies including "new memories" of torture at the hands of "satanic international cults" engaged in the rape, murder, and cannibalism of children. Social psychologist Richard Ofshe called the belief in satanic ritual abuse the "Achilles' heel" of the recovered memory movement, since the newly "remembered" reports of murder, cannibalism, and fetuses aborted in "rituals" not only sounded extreme and incredible but were not linked to corroborating evidence (e.g. many patients claiming "memories" of being ritually cut open for "sacrificial birth" had zero scars and upon OB-GYN exam had never given birth). Despite the lack of validating evidence as documented by the FBI's intensive, nation-wide investigation, in a national survey published in 1994, conducted by Gail Goodman and her colleagues, 13 percent of 7,000 therapists surveyed reported that they had "elicited recovered memories of ritual abuse", and these respondents "overwhelmingly believed" the "memories" were real. Two additional major studies—one

American, one British—came to the same conclusion as the FBI's Lanning in 1994. Funded with \$750,000 from the federal government, Gail Goodman and her team examined many thousands of patient's anecdotal stories of satanic ritual abuse and failed to find any corroborative evidence for the stereotypical, rote, detailed patient reports of multi-generational cults that sexually abused, killed, and/or ate children. (See, Ofshe, R. and Watters, E. (1996) Making Monsters: False Memories, Psychotherapy, and Sexual hysteria. 2nd Edition. University of California Press; See also, Pendergrast, M. (2017). The repressed memory epidemic: How it happened and what we need to learn from it. New York, NY: Springer.). Thus, prior to WPATH and prior to the ideological fervor of the Gender Affirmation Medical Enterprise, the Recovered Memory Therapy Industry had shown how "politically correct" ideological fervor can overcome a lack of credible scientific evidence and engage in unrproven, experimental "treatments" on tens of thousands of unsuspecting, vulnerable patients.

documented that the very similar to identical self-reported "memories" provided by "recovered memory" patients to law enforcement and the media were actually the result of memory contamination by unethical, pseudoscientific psychotherapy methods and media-therapist fueled social contagion fears of a criminally abusive "patriarchy". The patients' new, horrific pseudomemories were shown to be the result of ideologically driven pseudoscientific "treatments" including hypnosis, "age regression", dream interpretation, guided imagery, use of family photographs to stimulate "recovered memories", interpretation of physical symptoms as so-called "body memories", and coercive group therapy sessions similar to Maoist indoctrination groups. See, Ofshe, R. and Watters, E. (1996) Making Monsters: False Memories, Psychotherapy, and Sexual hysteria. 2nd Edition. University of California Press; See also, Pendergrast, M. (2017). The repressed memory epidemic: How it happened and what we need to learn from it. New York, NY: Springer.).

Subsequent research and many dozens of malpractice lawsuits and licensing revocations

Hundreds of lawsuits and media exposes shut down many of the Repressed Memory Therapy – Multiple Personality Disorder (RMT-MPD) clinics. State licensing boards then proceeded to revoke or restrict the licenses of multiple leaders of the RMT-MPD movement. See, e.g., Belluck, P. Memory Therapy Leads to a Lawsuit and Big Settlement [\$10.6 Million], The New York Times, Page 1, Column 1, Nov. 6, 1997; See also, Barden RC: Reforming the Mental Health System: Coordinated, Multidisciplinary Actions Ended "Recovered Memory" Treatments and Brought Informed Consent to Psychotherapy. Psychiatric Times. 2014;31(6): June 6, 2014.

It is important to note that the relevant professional associations including the American Medical Association, the American Psychiatric Association, the American Psychological Association and others (social worker and therapist associations, etc.) were not protective of the public and did little or nothing to expose the dangerous, pseudoscience fads and frauds of the RMT-MPD movement. In contrast, these political-professional associations protected the lucrative RMT-MPD industry that created tens of thousands of new patients requiring years of expensive treatments. The exposure of the dangers and damages of the RMT-MPD industry was done by a small number of civil attorneys, scientists, juries, and science-literate journalists. This example should give pause to those attempting to rush to fund and rapidly expand the experimental Gender Transition Industry.

In sum, some of the most tragic misadventures in the history of medicine involved the science illiterate reliance upon uncorroborated patient "stories"— self-reported evidence — as the sole basis for proceeding with controversial, experimental treatments on vulnerable patients (e.g. Lobotomies, Rolfing, Primal Screaming, Recovered Repressed Memories, Multiple Personality Disorder, Rebirthing Therapy, Coercive Holding Therapy, Reparenting, etc.). Understanding the important distinctions between scientifically valid-reliable, methodologically sound research

versus unreliable, anecdotal evidence and unverified patient "memories" is essential to efforts to protect the integrity of the scientific process as well as the quality and safety of medical care. Sex discordant gender ("transgender") assessments are currently made almost solely on unverified, uncorroborated "memory" reports of vulnerable patients.

36. PATIENTS' RIGHTS TO TESTED, PROVEN TREATMENTS and INFORMED CONSENT HAVE BEEN VIOLATED IN THE PAST BY ETHICAL FAILURES IN THE MEDICAL and MENTAL HEALTH SYSTEMS. USING EXPERIMENTAL PROCEDURES and UNPROVEN "TREATMENTS" ON UNINFORMED, VULNERABLE PATIENTS IS UNETHICAL and IMPROPER. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science — such is the case with the Gender Transition Industry. The history of the infamous Tuskegee studies, the Nazi and Imperial Japanese wartime experiments, lobotomies (e.g., Dr. Egas Moniz received the 1949 Nobel Prize in Medicine for inventing lobotomies as a "treatment" for schizophrenia! https://www.nobelprize.org/prizes/medicine/1949/moniz/article/), See, recovered therapy-multiple personality disorders, rebirthing therapy (see, e.g. See, Janofsky, M. Girl's Death Brings Ban on Kind of 'Therapy'. New York Times. April 18, 2001, See, also Peggy Lowe, Rebirthing team convicted: Two therapists face mandatory terms of 16 to 48 years in jail, Rocky Mountain News, April 21, 2001, coercive holding therapy (See, Hyde, J. "Holding therapy appears finished, State orders the last practitioner of holding therapy to end controversial method" Deseret News, Feb 13, 2005), and other tragic examples should serve as a stark warning to medical providers to properly protect the rights of patients and their families to a proper informed consent process and to not be subjected to experimental, unproven interventions such as gender transition

"treatments". It is now universally agreed that medical and psychotherapy patients have a right to proper informed consent. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedical conventions and declarations all protect patients' right to informed consent discussions of the risks and benefits of proposed treatments and alternative treatments including no treatment. See, Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998, ["Informed consent is defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks, and benefits, as well as of alternatives with their risks and benefits"]. See, also, Katz, A., Webb, S., and Committee on Bioethics, Informed Consent in Decision-Making **Pediatric** Practice, 2016, 138 (2) e20161485; DOI: in Pediatrics, August https://doi.org/10.1542/peds.2016-1485 at

https://pediatrics.aappublications.org/content/138/2/e20161485

Tragically, however, as I will discuss in detail below, we now have much evidence supporting increasing concerns that the true risks and benefits of Sex Discordant Gender ("transgender") transition "treatments" are NOT being properly and ethically presented to patients by providers (surgeons, endocrinologists, therapists, etc). Similarly, many of the published "pro-transition" research studies reviewed in this declaration have misrepresented to the public the actual risks and benefits of gender affirming medical interventions. The Gender Transition Industry has produced research claiming evidence supporting the use of controversial "treatments" when, in fact, their own study data more likely support the alternative hypothesis that so-called "transition" intervention procedures might produce higher risks of anxiety and more serious suicide attempts requiring hospitalization. (See detailed discussions below). Expert witnesses in cases involving issues related to Sex Discordant Gender Transition interventions are duty bound

and required by licensing rules to truthfully and fully disclose to courts and legal professionals *the well-documented risks, international controversies, and published misrepresentations* involving the still unproven Gender Transition methods and procedures.

37. METHODOLOGICAL ERRORS - ONE OF THE MOST SERIOUS OF ALL METHODOLOGICAL ERRORS, CONFIRMATION BIAS, PLAGUES THE RESEARCH OF THE GENDER TRANSITION INDUSTRY:

Confirmation bias is one of the most serious and potentially dangerous errors in the assessment-diagnosis-treatment process of medicine. One of the key methodologies in science and in proper investigations-assessments of all kinds — including expert witness review and testimony— is the generation and testing of multiple alternative investigative hypotheses. From US Public Junior High Schools (typically first taught to 8th Graders) through competent MA, MSW, and all Ph.D. and M.D. graduate programs, students and professionals at all levels are taught that the central methodology for science and for a proper assessment-diagnosis-treatment or expert witness report involves the generation and testing of alternative investigative hypotheses. Investigative hypotheses, once generated, should be rationally, properly, and fairly explored to see if actual, factual evidence supports or refutes the hypotheses. A common and serious error in improper assessments-diagnoses-treatments is "confirmation bias," the failure to generate and then explore alternative investigative-assessment-diagnostic hypotheses. In confirmation bias the science-naïve physician, investigator, expert, or therapist applies a narrow "tunnel vision" process to support a single, favorite, biased, pre-conceived hypothesis in a case. [See, Garb, H. N., & Boyle, P. A (2003). Understanding why some clinicians use pseudoscientific methods: Findings from research on clinical judgment. In S. O. Lilienfeld, S. J. Lynn, &. J. M. Lohr (Eds.), Science and pseudoscience in clinical psychology (pp. 17–38). New. York, NY: Guilford Press.;

See also, See, Plous, Scott (1993). The Psychology of Judgment and Decision Making. p. 233; Nickerson, Raymond S. (June 1998). "Confirmation Bias: A Ubiquitous Phenomenon in Many Guises". Review of General Psychology 2 (2): 175-220. doi:10.1037/1089-2680.2.2.17; See, Joshua Klayman and Young-Won Ha, Confirmation, Disconfirmation, and Information in Hypothesis Testing, Psychological Review, 1987, Vol.94, No. 2, 211-228.] Currently, too many Gender Transition Industry advocate-activist-providers appear to violate the requirement to properly generate, explore, and disclose alternative hypotheses for assessments-diagnoses and treatments. In my opinion such failures, including the activist-ideologue demand that all alternative hypotheses and treatments be banned as forms of "conversion" therapy, risk institutionalizing confirmation bias —a dangerous form of negligent practice. See, Smith, T. Summary of AMA Journal of Ethics article on cognitive biases, Four widespread cognitive biases and how doctors can overcome them (e.g., confirmation bias, anchoring bias, affect heuristic, and outcomes bias) at https://www.ama-assn.org/delivering-care/ethics/4-widespread-cognitivebiases-and-how-doctors-can-overcome-them. ("Physicians are human and, therefore, constantly vulnerable to cognitive bias. But this imperfection is not just theoretical. It can have huge effects on patient care.")

38. METHODOLOGICAL ERRORS of the GENDER t INDUSTRY- CONFIRMATION BIAS CAN PREVENT COMPLEX, COMPREHENSIVE DIAGNOSIS AND TREATMENT EXPLORING ALTERNATIVE HYPOTHESES:

By demanding the immediate and un-investigated "affirmation" of a Sex Discordant Gender Identity ("transgender") patient's requests for so-called" transitioning" — without conducting a detailed, proper, medical assessment of alternative hypotheses — the Gender Transition Industry is attempting to enforce and institutionalize the methodological failure of "confirmation bias". By

labelling all forms of psychotherapy, coping and resilience training, cognitive behavioral therapy for depression-anxiety, or other options as "conversion therapy", the Gender Transition Industry is failing to treat individual patients according to the basic requirements and principles of competent medical assessment, diagnosis, and treatment. As I will discuss in detail in the methodological analyses below, the current scientific evidence does not support the current treatments nor methods endorsed and aggressively marketed and demanded by the Gender Transition Industry. The Gender Transition Industry's general refusal to properly investigate or even consider alternative hypotheses, alternative diagnoses, and alternative treatments is, in my view, unethical misconduct. For example, many peer reviewed, properly conducted, published research reports demonstrate that cognitive-behavioral therapy is a very low-risk, safe, and highly effective treatment for depression and anxiety disorders. See, e.g., Mor N, Haran D. Cognitivebehavioral therapy for depression. J Psychiatry Relat Sci. 2009;46(4):269-73. PMID: 20635774, https://pubmed.ncbi.nlm.nih.gov/20635774/; [A review of "Twenty-nine Random Control Trials were included in three separate meta-analyses. Results showed multi-modal CBT was more effective than no primary care treatment (d =0.59), and primary care treatment-as-usual (TAU) (d = 0.48) for anxiety and depression symptoms."] See, e.g., Twomey, C., O'Reilly, G. and Byrne, M. Effectiveness of cognitive behavioural therapy for anxiety and depression in primary care: a meta-analysis, Family Practice, Volume 32, Issue 1, February 2015, Pages 3–15, https://doi.org/10.1093/fampra/cmu060. The political taint is so strong that some activistproviders reportedly fail to offer and engage in CBT therapy with depressed-anxious Gender Dysphoric patients for fear of being attacked as engaging in "conversion" therapy. Again, the institutionalization of medical negligence (e.g., confirmation bias) harms vulnerable patients.

- 39. PROPER INVESTIGATIONS OF DECEPTIVE MISCONDUCT Ideological Overreach can Lead to Unethical Misconduct and Licensing Violations. Misrepresenting medical-scientific research, deceptively hiding methodological errors, or failing to honestly report ongoing international controversies to courts, patients, or guardians should be properly investigated as misconduct. Licensing boards and professional associations produce and should properly enforce ethics rules and requirements governing the conduct of health care professionals to protect the rights of patients and parents.
- 40. PROPER INVESTIGATIONS OF DECEPTIVE MISCONDUCT Plaintiffs' EXPERT DR BROWN's METHODOLOGICAL FAILURES SHOULD BE INVESTIGATED: In my opinion, Plaintiffs' expert Dr. Brown, appears to have engaged in misconduct by his signed opinion in this case stating "Nor is there any uncertainty or dispute in the medical field regarding the medical necessity of this care." As the detailed methodological analysis below amply documents, Dr. Brown's expert declaration in this case appears to document an example of unusual ignorance or potentially, a deceptive failure to properly report on, and inform the court of, the ongoing international controversies and debates regarding Gender Transition interventions ("treatments") (e.g. See the relevant multiple, national science reviews cited below from Great Britain, Sweden, and Finland, as well as the Cochrane Review all exposing the serious methodological defects, controversies, and methodological failings of Gender Transition research as documented below).
- 41. THE ACTUAL PREVALENCE OF GENDER DYSPHORIA and PATIENTS THAT IDENTIFY AS GENDER DISCORDANT ("transgender") IS UNKNOWN BUT IT APPEARS TO BE INCREASING AT A RAPIDLY ACCELERATING RATE THUS SUPPORTING AN ALTERNATIVE HYPOTHESIS OF SOCIAL CONTAGION: Estimates reported in in the DSM-

V (a diagnostic manual that functions via voting and more as a dictionary than a valid scientific methodology) were between 0.005% to 0.014% for adult males and 0.002% to 0.003% for adult females. Thus, gender dysphoria was, until just a few years ago, a very rare condition. It is currently unknown whether these DSM estimates were falsely low due to under-reporting or:

- whether changing societal acceptance of transgendered identity and the growing number of medical centers providing interventions for gender dysphoria has led to increased reporting of persons who identify as transgender
- or whether the reported educational programs aggressively promoting "non-binary" identification to elementary to high school students to college students have greatly increased the numbers of youth adopting a transgender identity
- or whether the reported wave of "trans You Tube influencers" watched by millions each day as they aggressively "sell" the transgender lifestyle has added to a social contagion effect with vulnerable lonely, depression, anxious, or autistic youth.
 - or other causal process.

A key unanswered research question is whether a social contagion process is leading to vast and rapid increases in the numbers of patients identifying as gender discordant ("transgender"). How many of the new waves of thousands of cases are 'false reports' that will dissipate with time and normal development over time? For example, the Gender Identity Development Service in the United Kingdom, which treats only children under the age of 18, reported that it received 94 referrals of children in 2009/2010 and 1,986 referrals of children in 2016/2017 a relative increase of 2,000%. See, "GIDS referrals figures for 2016/17," Gender Identity Development Service, GIDS. NHS.uk (undated), http://gids.nhs.uk / sites / default / files /content_uploads /referralfigures-2016- 17.pdf.

Reportedly, similar social contagion processes led to tens of thousands of patients and families being harmed by controversial diagnoses such as multiple personality disorder" (MPD and controversial interventions including "recovered memory therapy (RMT). RMT and MPD patients, once considered extremely rare (some 300 MPD patients reported worldwide prior to the 1980s-1990s social contagion epidemic) erupted into a flood of tens of thousands of patients and affected families in the 1990s. These very controversial disorders and treatments were greatly reduced by dozens of civil lawsuits against RMT-MPD therapists, international news exposure of scientific evidence debunking these notions, and international news reporting of the civil litigation, licensing prosecutions, and licensing revocations of well-known RMT-MPD practitioners. (See, e.g., Belluck, P. Memory Therapy Leads to a Lawsuit and Big Settlement [\$10.6 Million], The New York Times, Page 1, Column 1, Nov. 6, 1997; Pendergrast, M. (2017). The repressed memory epidemic: How it happened and what we need to learn from it. New York, NY: Springer).

Recent data indicates that the number of people seeking care for gender dysphoria is rapidly increasing with some estimates as high as 20-fold and more. See, Chen, M., Fuqua, J. & Eugster, E. A. Characteristics of Referrals for Gender Dysphoria Over a 13-Year Period. Journal of Adolescent Health 58, 369-371, doi:https://doi.org/10.1016/j.jadohealth.2015.11.010 (2016); 4. "GIDS referrals figures for 2016/17," Gender Identity Development Service, GIDS.NHS.uk (undated), http://gids.nhs.uk/sites/default/files/content_uploads/referral-figures-2016-17.pdf.)
See, Zucker K. J. (2017). Epidemiology of gender dysphoria and transgender identity. Sexual health, 14(5), 404-411. https://doi.org/10.1071/SH17067. Data from England show increases of 4,000% for female to male patients and in America data show increases of 20,000% for young women (e.g. from .01 to 2%). Estimates vary considerably in relation to how sex-gender identity discordance is defined. See, Zhang, Q., Goodman, M., Adams, N., Corneil, T., Hashemi, L.,

Kreukels, B., Motmans, J., Snyder, R., & Coleman, E. (2020). Epidemiological considerations in transgender health: A systematic review with focus on higher quality data. *International journal of transgender health*, 21(2), 125–137. https://doi.org/10.1080;; Poteat, T., Rachlin, K., Lare, S., Janssen, A. & Devor, A. in *Transgender Medicine: A Multidisciplinary Approach* (eds Leonid Poretsky & Wylie C. Hembree) 1-24 (Springer International Publishing, 2019); Flores AR, Herman JL, Gates, GJ, Brown TNT. How Many Adults Identify as Transgender in the United States? Los Angeles, CA: The Williams Institute; 2016. https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Adults-US-Aug-2016.pdf. Accessed April 28, 2021.

- 42. EVIDENCE SUPPORTS THE HYPOTHESIS THAT GENDER IDENTITY IS *NOT* GENETICALLY NOR BIOLOGICALLY DETERMINED: There is strong disconfirming evidence (e.g., Popperian falsifiability) against the theory that gender identity is determined at or before birth and is unchangeable. This comes from A) identical twin studies where siblings share genetic complements and prenatal environmental exposure but have differing gender identities. See, Heylens, G. et al. Gender identity disorder in twins: a review of the case report literature. J Sex Med 9, 751-757, doi:10.1111/j.1743-6109.2011.02567.x (2012) and B) the very recent and massive increase in the numbers of GD patients over a very short time span. This argues against a biological-genetic hypothesis. See Leinung MC, Joseph J. Changing Demographics in Transgender Individuals Seeking Hormonal Therapy: Are Trans Women More Common Than Trans Men? Transgend Health. 2020 Dec 11;5(4):241-245. doi: 10.1089/trgh.2019.0070. PMID: 33644314; PMCID: PMC7906237.
- 43. REPLICATED RESEARCH EVIDENCE SUPPORTS THE HYPOTHESIS THAT GENDER IDENTITY IS *NOT* IMMUTABLE: Further evidence that gender identity is not fixed and immutable comes from established peer reviewed literature demonstrating that the vast

majority (80-95%) of children who express gender dysphoria revert to a gender identity concordant with their biological sex by late adolescence. This natural developmental "cure" of gender dysphoria requires no direct "treatment" and prevents the hormonal and surgical destruction of normal, healthy organs and bodily processes (e.g. prevents sterilization of the child). See Singh D, Bradley SJ, Zucker KJ. A Follow-Up Study of Boys With Gender Identity Disorder. Front Psychiatry. 2021 Mar 29;12:632784. doi: 10.3389/fpsyt.2021.632784. PMID: 33854450; PMCID: PMC8039393. It is not currently known whether individuals with gender dysphoria persistence have differing etiologies or severity of precipitating factors compared to desisting individuals. See, Drummond, K. D., Bradley, S. J., Peterson-Badali, M. & Zucker, K. J. A follow-up study of girls with gender identity disorder. Dev Psychol 44, 34-45, doi:10.1037/0012-1649.44.1.34 (2008); Steensma, T. D., McGuire, J. K., Kreukels, B. P., Beekman, A. J. & Cohen-Kettenis, P. T. Factors associated with desistence and persistence of childhood gender dysphoria: a quantitative follow-up study. J Am Acad Child Adolesc Psychiatry 52, 582-590, doi:10.1016/j.jaac.2013.03.016 (2013).

44. VIRTUALLY ALL TRANSGENDER PATIENTS ARE BORN WITH HEALTHY NORMAL SEX ORGANS AND NO KNOWN BRAIN OR GENETIC ABNORMALITIES: Most people with gender dysphoria, do not have a disorder of sexual development. As documented in their medical record, such patients typically have normally formed sexual organs. The presence of normal, functional sex organs prior to the initiation of hormone administration or surgical "transition" operations is typical in transgender patients. I note that hormonal treatments and surgery to remove healthy, normal organs (the genitals of GD patients) both destroy the function of healthy organs (e.g., producing the life-long sterilization of GD patients). Such so-called apparently injurious "treatments" are very controversial and occur nowhere else in medicine that

I am aware of with the exception of requests for the amputation of healthy limbs in patients suffering from the very controversial "body integrity identity disorder". See, Elliott, T., Body Dysmorphic Disorder, Radical Surgery and the Limits of Consent, *Medical Law Review*, Volume 17, Issue 2, Summer 2009, Pages 149–182, https://doi.org/10.1093/medlaw/fwp001 [In 2000 there was a media furor, when it was disclosed that a Scottish surgeon had operated upon two adult male patients reportedly suffering from a rare form of a psychological condition known as body integrity identity disorder, in each case amputating a healthy leg. Since then, the question of whether such surgery is ethically or legally permissible has been a matter of debate. The subject raises issues as to the extent to which it is proper to treat adults with psychiatric or psychological disorders with radical surgery, particularly where the appropriate diagnosis and treatment of the underlying disorder is uncertain or disputed]. Similarly, Gender Transition interventions also involve treating patients "with psychiatric or psychological disorders with radical surgery, where the appropriate diagnosis and treatment of the underlying disorder is uncertain or disputed."

The primary use of psychotherapy as a means to treat body dysmorphic disorder contrasts with the approaches used by the Gender Transition Industry. See, Hadley, S. J., Greenberg, J., & Hollander, E. (2002). Diagnosis and treatment of body dysmorphic disorder in adolescents. *Current psychiatry reports*, 4(2), 108–113. https://doi.org/10.1007/s11920-002-0043-4; Allen, A., & Hollander, E. (2000). Body dysmorphic disorder. *The Psychiatric clinics of North America*, 23(3), 617–628. https://doi.org/10.1016/s0193-953x(05)70184-2

45. THE ETIOLOGY (CAUSE) OF GENDER DYSPHORIA IS CURRENTLY UNKNOWN and the "TREATMENTS" are of UNCERTAIN EFFICACY - THUS THE CURRENT THEORIES and TREATMENTS REMAIN EXPERIMENTAL and CONTROVERSIAL: The etiology of gender dysphoria in individuals with sex-gender identity

discordance remains unknown. Alternative hypotheses include some as yet unidentified biological cause, prenatal hormone exposure, genetic variation, postnatal environmental influences, family dynamics, other forms of mental illness, an abnormal detour from developmental identity processes, social contagion effects on suggestible-vulnerable subjects, or a combination of multiple factors. Based upon the available evidence, it is most likely that sex-gender identity discordance is multifactorial with both genetic and environmental influences, differing in both kind and degree in any affected individual. Importantly, these potential contributing factors are hypothesized to be contributory, but not determinative of the condition. See, Saleem, Fatima, and Syed W. Rizvi. "Transgender Associations and Possible Etiology: A Literature Review." Cureus 9, no. 12 (2017): e1984

46. THE CONCEPT OF "NEUROLOGICAL SEX" IS EXPERIMENTAL, UNVERIFIED, HAS NO KNOWN ERROR RATE and is NOT ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY: The recently coined concept of "neurological sex" as a distinct entity or a basis for classifying individuals as male or female has no scientific justification. Limited emerging data has suggested structural and functional differences between brains from normal and transgender individuals. These data do not establish whether these differences are innate and fixed or acquired and malleable. The remarkable neuronal plasticity of the brain is well known, well documented, and has been studied extensively in gender-independent contexts related to health and disease, learning, and behavior. See, Fatima Yousif Ismail, Ali Fatemi, and Michael V. Johnston, "Cerebral Plasticity: Windows of Opportunity in the Developing Brain," European Journal of Paediatric Neurology 21, no. 1 (2017).

47. GENDER IDENTITY IDEOLOGY IS A POLITICAL, NOT SCIENTIFIC THEORY:

A key alternative investigative hypothesis in efforts to understand the rise of reports of gender

discordance and social-political-medical attempts to create a transgender movement is that such ideas are not based upon sound scientific biological, genetic, or related principles and data but rather are based upon ideology and driven by political advocacy. Although worldviews among scientists and physicians differ widely, similar to society at large, science must remain firmly grounded in testable, valid, and reliable assessments of physical reality — not ideologically tainted perceptions and belief systems. The inherent link between human sexual biology and teleology (e.g. human reproduction) is self-evident and fixed. Breithaupt H. The science of sex. *EMBO Rep.* 2012;13(5):394. Published 2012 May 1. doi:10.1038/embor.2012.45. As an investigative hypothesis, the historical foundation of gender identity ideology appears to be grounded in Critical Theory, which may provide a basis to understand the level of extreme methodological confusion, defects, and errors in the Gender Transition Industry. For example, "transgender" activists often support clearly contradictory theories and arguments at the same time (e.g. the claim that Gender Dysphoria (GD) and "trans identity" are "immutable", "genetic", or based on "brain structures" while simultaneously claiming GD is also "fluid" and thus capable of changing on a daily basis). Association of critical theory with the Gender Transition Industry reflects a controversial ideological foundation for the provision of hormonal and surgical interventions that have potential to permanently damage essential bodily functions including the sterilization of vulnerable patients. (See, e.g., Pluckrose, and Lindsay, J., Cynical Theories: How Activist Scholarship Made Everything about Race, Gender, and Identity—and Why This Harms Everybody, Pitchstone Publishing, August 25, 2020).

48. GENDER IDENTITY IDEOLOGY and the GENDER TRANSITION INDUSTRY--INCLUDING INTERVENTIONS -- HAVE NO RELIABLE-VALID SCIENTIFIC BASIS and HAVE NEVER BEEN ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY and

HAVE NO KNOWN NOR PUBLISHED ERROR RATE: The political-ideological claims of proponents of transgenderism, which include opinions such as "Gender identity is the primary factor determining a person's sex" and "Gender is the only true determinant of sex" and individuals have "sex assigned at birth" must be viewed in their proper philosophical context. There is no scientific basis for redefining sex on the basis of a person's subjective, psychological sense of 'gender'.

49. IN CONTRAST TO SEX DISCORDANT GENDER "TRANSGENDER" IDEOLOGY, THE BIOLOGICAL BASIS OF SEX IS FIRMLY GROUNDED IN VALID-RELIABLE SCIENCE, ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY AND HAS A VERY LOW ERROR RATE: The prevailing, constant, tested, proven, and accurate designation of sex as a biological trait grounded in the inherent purpose of male and female anatomy and as manifested in the appearance of external genitalia at birth remains the proper scientific and medical standard. Redefinition of the classification and meaning of sex based upon pathologic variation is not established medical fact. See, e.g., Mittwoch, U. (2013), Sex determination. EMBO reports, 14: 588-592. https://doi.org/10.1038/embor.2013.84

Potential Harm to Vulnerable Patients Resulting from Experimental Gender Dysphoria Treatments

50. THE ETHICAL FOUNDATIONS of MEDICINE — FIRST DO NO HARM: The fundamental purpose of the practice of medicine is to treat disease and alleviate suffering. An essential tenet of medical practice is to avoid doing harm in the process. Efforts to rely upon clear, valid, reliable, and definitive evidence on how to best accomplish treatment goals is the essential ethical, professional, scientific, and clinical goals of physicians. The current Gender Transition Industry violates this essential principle by using experimental treatments on vulnerable

populations without properly informing them of the actual risks and limitations of the treatments. See, Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998.

- 51. THE ETHICAL FOUNDATIONS of MEDICINE — REQUIRE US TO STRIVE TO HELP THOSE IN DISTRESS WITH COMPASSION, KINDNESS, and EMPATHY AND TO NOT VIOLATE PATIENTS' and PARENTS' RIGHTS BY ENGAGING IN EXPERIMENTAL, UNPROVEN, INTERVENTIONS ("TREATMENTS") LEADING POTENTIAL TO PERMANENT DAMAGE TO MANY PATIENTS – INCLUDING STERILIZATION: Persons with gender dysphoria as defined in the DSM-V report experiencing significant psychological distress related to their condition with elevated risk of depression, suicide, and other morbidities. Thus, attempts to provide effective medical care to affected persons are clearly warranted. Efforts to effectively treat persons with gender dysphoria require respect for the inherent dignity of those affected, sensitivity to their suffering, and maintenance of objectivity in assessing etiologies and long-term outcomes. In my opinion, the use of unproven, experimental treatments on vulnerable patients and the publication of grossly methodologically defective research are violations of the ethical foundations of medicine.
- 52. IN THE ETHICAL PRACTICE OF MEDICINE, VALID-RELIABLE SCIENCE SHOULD PRECEDE INVASIVE, RISKY, DAMAGING TREATMENT PROTOCOLS THREE CURRENT APPROACHES: There is an urgent need for high quality controlled clinical research trials to determine ways to develop supportive dignity affirming social environments that maintain affirmation of the *scientifically accepted biological reality*. To date, three approaches have been proposed for managing children with gender dysphoria. See, Zucker, K. J. On the "natural history" of gender identity disorder in children. J Am Acad Child Adolesc Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008).) The first approach, often referred to

as "conversion" or "reparative therapy", is directed toward actively supporting and encouraging children to identify with their biological sex. The second "neutral" or "watchful waiting" approach, motivated by understanding of the natural history of transgender identification in children, is to neither encourage nor discourage transgender identification, recognizing that the vast majority of affected children if left alone are likely to eventually realign their reports of gender identification with their sex. This approach may also include the use of scientifically validated treatments (e.g. CBT) for the patient's anxiety, depression, social skills deficits or other issues. See, van Bentum, J. S., van Bronswijk, S. C., Sijbrandij, M., Lemmens, L., Peeters, F., Drukker, M., & Huibers, M. (2021). Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression. Depression and anxiety, 10.1002/da.23151. Advance online publication. https://doi.org/10.1002/da.23151; Gallagher, M. W., Phillips, C. A., D'Souza, J., Richardson, A., Long, L. J., Boswell, J. F., Farchione, T. J., & Barlow, D. H. (2020). Trajectories of change in well-being during cognitive behavioral therapies for anxiety disorders: Quantifying the impact and covariation with improvements in anxiety. Psychotherapy (Chicago, Ill.), 57(3), 379–390. https://doi.org/10.1037/pst0000283. The third "affirming" approach is to actively encourage children to embrace transgender identity with social transitioning followed by hormonal therapy leading to potential surgical interventions and life-long sterilization. See, Walch A, Davidge-Pitts C, Safer JD, Lopez X, TangprichaV, Iwamoto SJ. Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective.J Clin Endocrinol Metab. 2021;106(2):305-308. doi:10.1210/clinem/dgaa816.

53. ANOTHER CONTROVERSY — THE "WATCHFUL WAITING" TREATMENT MODALITY INVOLVES NO MEDICAL TREATMENT AND IS CURRENTLY THE BEST SCIENTIFICALLY SUPPORTED INTERVENTION FOR YOUNG CHILDREN REPORTING

GENDER DYSPHORIA: Desistance (i.e. realignment of expressed gender identity to be concordant with sex) provides the greatest lifelong benefit and is the outcome in the vast majority of patients and should be maintained as a desired goal. Any coerced, required, societally mandated, scientifically untested, intervention that would or could unnecessarily interfere with the likelihood of a normal, non-traumatic, developmental, resolution of gender dysphoria is unwarranted and potentially harmful. The gender affirming approach, which includes use of a child's preferred pronouns, use of sex-segregated bathrooms, other intimate facilities and sleeping accommodations corresponding to a child's gender identity, has limited, "very weak", "sparse" scientific support for short-term alleviation of dysphoria and no long-term outcomes data demonstrating superiority over the other approaches. (See, National reviews of England, Sweden, Finland, the Cochrane review, the Griffin review, the Carmichael review and others). Claims that the other approaches have been scientifically disproven are simply false. In stark contrast to the ideologically tainted, "voted in", recommendations of Professional Associations, decades of peerreviewed, published scientific research, including the pioneering work of Dr. Kenneth Zucker, have supported the efficacy of a more conservative "watchful waiting" approach for the majority of patients experiencing gender dysphoria. See, Zucker, K. J. On the "natural history" of gender identity disorder in children. J Am Acad Child Adolesc Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008); Bradley, S. J. & Zucker, K. J. Gender Identity Disorder: A Review of the Past 10 Years. Journal of the American Academy of Child & Adolescent Psychiatry 36, 872-880, doi:10.1097/00004583-199707000-00008.). In sum, the treatment protocols and recommendations of politically influenced, non-science associations (WPATH, Pediatrics Assn, APA) who engaged in "voting", consensus-seeking methodologies (not science)

are not accepted by the relevant *scientific* community, are not based upon competent-credible, methodologically sound science, and have no known, nor published error rate.

54. HARMFUL EFFECTS OF AFFIRMATION TREATMENT — INCLUDING EFFECTS OF PUBERTAL SUPPRESSION TREATMENTS ARE ESTABLISHED and ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY:

"To sum up how puberty suppression works, a thought experiment might be helpful. Imagine two pairs of biologically and psychologically normal identical twins -a pair of boys and a pair of girls -where one child from each pair undergoes puberty suppression and the other twin does not. Doctors begin administering GnRH analogue treatments for the girl at, say, age 8, and for the boy at age 9. Stopping the gonadal hormone pathway of puberty does not stop time, so the pubertysuppressed twins will continue to age and grow -and because adrenal hormones associated with puberty will not be affected, the twins receiving GnRH analogue will even undergo some of the changes associated with puberty, such as the growth of pubic hair. However, there will be major, obvious differences within each set of twins. The hormone suppressed twins' reproductive organs will not mature: the testicles and penis of the boy undergoing puberty suppression will not mature, and the girl undergoing puberty suppression will not menstruate. The boy undergoing puberty suppression will have less muscle mass and narrower shoulders than his twin, while the breasts of the girl undergoing puberty suppression will not develop. The boy and girl undergoing puberty suppression will not have the same adolescent growth spurts as their twins. So all told, by the time the untreated twins reach maturity, look like adults, and are biologically capable of having children, the twins undergoing puberty suppression will be several inches shorter, will physically look more androgynous and childlike, and will not be biologically capable of having children. This is a thought experiment, but it illustrates some of the effects that puberty suppression would

be expected to have on the development of a growing adolescent's body." See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36.

55. METHODOLOGICAL FLAWS IN THE GENDER TRANSTION INDUSTRY— THE ENDOCRINE SOCIETY HAS REPORTED THAT THE QUALITY OF EVIDENCE FOR GENDER DYSPHORIA TREATMENTS IS CURRENTLY "LOW OR VERY LOW" (Key Quote: "ANY estimate of effect is VERY uncertain") — THUS THERE IS CLEARLY NO GENERAL ACCEPTANCE IN THE RELEVANT SCIENTIFIC COMMUNITY AND THE ERROR RATE IS UNKNOWN and COULD WELL BE VERY HIGH: The Endocrine Society published 2009 clinical guidelines for the treatment of patients with persistent gender dysphoria. See, Hembree, W. C. et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 94, 3132-3154, doi:10.1210/jc.2009-0345 (2009). The recommendations include temporary suppression of pubertal development of children with GnRH agonists (hormone blockers normally used for children experiencing precocious puberty) followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. In developing these guidelines, the authors assessed the quality of evidence supporting the recommendations made with use of the GRADE (Recommendations, Assessment, Development, and Evaluation) system for rating clinical guidelines. As directly stated in the Endocrine Society publication, "the strength of recommendations and the quality of evidence was low or very low." According to the GRADE system, low recommendations indicate "Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate." Very low recommendations mean that "any estimate of effect is very uncertain". (See, Guyatt G H,

Oxman A D, Vist G E, Kunz R, Falck-Ytter Y, Alonso-Coello P et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations BMJ 2008; 336:924 doi:10.1136/bmj.39489.470347.AD). An updated set of guidelines was published in September of 2017. See, Hembree, W. C. et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, doi:10.1210/jc.2017-01658 (2017). The low quality of evidence presented in this document persists to the current day as *the controversy over these "treatments" is accelerating in recent years*.

56. METHODOLOGICAL FLAWS IN RESEARCH of the GENDER TRANSITION INDUSTRY—THE WPATH GUIDELINES (7th version) NOTE SERIOUS LIMITATIONS OF THE EXISTING SCIENTIFIC DATA: Clinical Practice Guidelines published by the World Professional Association for Transgender Health (WPATH) - (an advocacy-political, consensus-seeking organization, whose positions are based on voting and not a scientific, evidence-based process) which is currently in its 7th iteration, similarly, though less explicitly, acknowledge the limitation of existing scientific data supporting their recommendations given and "the value of harm-reduction approaches". Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W. J., Monstrey, S., Adler, R. K., Brown, G. R., Devor, A. H., Ehrbar, R., Ettner, R., Eyler, E., Garofalo, R., Karasic, D. H., Zucker, K. (2012). Standards of care for the health of transsexual, transgender, and gendernonconforming people, version 7. International Journal of Transgenderism, 13(4), 165–232. https://doi.org/10.1080/15532739.2011.700873

57. INTERVENTIONS ("TREATMENTS") OF CHILDREN WITH POTENTIALLY HARMFUL HORMONES TO INTERVENE IN THE LIFE OF A CHILD WHO IS HIGHLY

LIKELY (80%+) TO RESOLVE THE GENDER DYSPHOTIA ISSUE NATURALLY — IS RISKY, UNSCIENTIFIC and UNETHICAL. IATROGENIC DAMAGES TO PATIENTS — INCLUDING LIFE-LONG STERILITY, STUNTED GROWTH, INCREASED HEART ATTACK RISKS, ETC. — ARE OFTEN IRREVERSIBLE: Treatment of gender dysphoric children who experience persistence of symptoms with hormones (pubertal suppression and crosshormone therapy) carries significant risk. It is generally accepted, even by advocates of transgender hormone therapy, that hormonal treatment impairs fertility and often result in sterility, which in many cases is irreversible. See, Nahata, L., Tishelman, A. C., Caltabellotta, N. M. & Quinn, G. P. Low Fertility Preservation Utilization Among Transgender Youth. Journal of Adolescent Health 61, 40-44, doi:https://doi.org/10.1016/j.jadohealth.2016.12.012 (2017)). Emerging data also show that treated patients have lower bone density which may lead to increased fracture risk later in life. See, Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M. & Rotteveel, J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. The Journal of Clinical Endocrinology & Metabolism 100, E270-E275, doi:10.1210/jc.2014-2439 (2015)). Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease. See, Seal, L. J. A review of the physical and metabolic effects of cross-sex hormonal therapy in the treatment of gender dysphoria. Annals of Clinical Biochemistry 53, 10-20, doi:10.1177/0004563215587763 (2016); Banks, K., Kyinn, M., Leemaqz, S. Y., Sarkodie, E., Goldstein, D., & Irwig, M. S. (2021). See also, Blood Pressure Effects of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Adults. Hypertension (Dallas, Tex.: 1979), HYPERTENSIONAHA12016839. Advance online publication.

https://doi.org/10.1161/HYPERTENSIONAHA.120.16839; Getahun, D., Nash, R., Flanders, W. D., Baird, T. C., Becerra-Culqui, T. A., Cromwell, L., Hunkeler, E., Lash, T. L., Millman, A., Quinn, V. P., Robinson, B., Roblin, D., Silverberg, M. J., Safer, J., Slovis, J., Tangpricha, V., & Goodman, M. (2018). Cross-sex Hormones and Acute Cardiovascular Events in Transgender Study. medicine. Persons: Α Cohort Annals of internal 169(4),205–213. https://doi.org/10.7326/M17-2785; Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, The Journal of Clinical Endocrinology & Metabolism, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643.

58. LONG TERM EFFECTS OF THE CURRENT EXPERIMENTAL "GENDER AFFIRMING" MEDICAL INTERVENTIONS — FOR CHILDREN and ADULTS — *ARE UNKNOWN and UNPROVEN* — THIS HAS BEEN WELL KNOWN SINCE 2011 and EARLIER. SUCH TREATMENTS ARE *NOT* GENERALLY ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY and HAVE *NO* KNOWN NOR PUBLISHED ERROR RATE. CURRENT GENDER TRANSITION INDUSTRY STUDIES OFTEN SUFFER FROM SEVERE METHODOLOGICAL LIMITATIONS: Since strategies for the treatment of transgendered children as summarized by the Endocrine Society guidelines are relatively new, long-term outcomes are unknown. Evidence presented as support for short-term reductions in psychological distress following social transition in a "gender affirming" environment remains inconclusive. When considered apart from advocacy-based agendas, multiple potential confounders are evident. The most notable deficiencies of existing research are the absence of proper control subjects and lack of randomization in study design. See, Hruz, P. W. Deficiencies

in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q* 87, 34-42, doi:10.1177/0024363919873762 (2020). Although appropriate caution is warranted in extrapolating the outcomes observed from prior studies with current treatments, adults who have undergone social transition with or without surgical modification of external genitalia continue to have *rates of depression, anxiety, substance abuse and suicide far above the background population*. See, Adams, N., Hitomi, M. & Moody, C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health 2, 60-75, doi:10.1089/trgh.2016.0036 (2017); See also, Dhejne, C. et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011)).

59. MEDICAL TREATMENTS BASED ON PSEUDO-SCIENCE and POLITICAL IDEOLOGIES CONTRARY TO THE RELEVANT-RELIABLE-VALID SCIENCE COULD RESULT IN IRREVERSIBLE HARMS TO MANY PATIENTS WHO WOULD OTHERWISE HAVE RECOVERED NATURALLY FROM GENDER DYSPHORIA: Of particular concern is the likelihood that forced-coerced, or naively requested gender transition "treatments" and social changes could interfere with known very high rates of natural-untreated resolution of sex-gender discordance. Any activity that encourages or perpetuates transgender persistence for those who would otherwise desist could cause significant harm, particularly in light of the current treatment paradigm for persisting individuals. As noted, sterility can often be expected with hormonal or surgical disruption of normal gonadal function. See, Cheng PJ, Pastuszak AW, Myers JB, Goodwin IA, Hotaling JM. Fertility concerns of the transgender patient. Transl Androl Urol. 2019 Jun;8(3):209-218. doi: 10.21037/tau.2019.05.09. PMID: 31380227; PMCID: PMC6626312.

- or ARE NOT COMPETENT TO GIVE INFORMED CONSENT TO PROCEED WITH EXPERIMENTAL, HAZARDOUS TREATMENTS THAT COULD POTENTIALLY RESULT IN PERMANENT STERILITY: This is a particularly concerning issue given that children are likely to be incapable of giving truly informed consent. See, Geier, C. F. Adolescent cognitive control and reward processing: Implications for risk taking and substance use. Hormones and Behavior 64, 333-342, doi:https://doi.org/10.1016/j.yhbeh.2013.02.008 (2013). This concern remains valid when applied to hormonal or surgical treatments that will result in lifelong sterility. In addition, parents are often manipulated and coerced by misinformed political activists or providers who threaten them with dire warnings that the only two options are "treatment or suicide". These "threats" ignore data that challenge this biased assumption. See, D'Angelo, R., Syrulnik, E., Ayad, S. *et al.* One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav* **50**, 7–16 (2021). https://doi.org/10.1007/s10508-020-01844-2
- 61. AN ALTERNATIVE HYPOTHESIS FOR THE RAPID INCREASE IN GENDER DYSPHORIA SOCIAL CONTAGION PROCESSES HAS BEEN IMPROPERLY IGNORED BY TRANSGENDER ACTIVISTS and PROVIDERS: Social and psychological support with dignity for adolescents with gender dysphoria does not necessitate acceptance of a unproven, experimental understanding of human sexuality in schools. Rather, policy requirements including social contagion promoting educational processes that can increase the prevalence and persistence of transgender identification have significant potential for inducing long-term harm to affected children.
- 62. COMPETENT, METHODOLOGICALLY SOUND, LONG-TERM TREATMENT OUTCOME RESEARCH ON GENDER DYSPHORIA INTERVENTIONS HAS NEVER BEEN

DONE: There remains a significant and unmet need to improve our understand of the biological, psychological, and environmental basis for the manifestation of patient reports of discordance of gender identity and biological sex in affected individuals. (Olson-Kennedy, J. et al. Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes. Current Opinion in Endocrinology, Diabetes and Obesity 23, 172-179, doi:10.1097/med.00000000000000236 (2016)). In particular, there is a concerning lack of randomized controlled trials comparing outcomes of youth with gender dysphoria who are provided public encouragement for "affirming" social gender transition and how such transitioning affects the usual and natural progression to resolution of gender dysphoria in most affected children. Such studies can be ethically designed and executed with provisions for other dignity affirming measures to both treatment groups. See Sugarman J. Ethics in the design and conduct of clinical trials. Epidemiol Rev. 2002;24(1):54-8. doi: 10.1093/epirev/24.1.54. PMID: 12119856; And https://clinicalcenter.nih.gov/recruit/ethics.html

GENDER AFFIRMING ("TRANSITION") INTERVENTIONS REMAIN EXPERIMENTAL and HIGHLY CONTROVERSIAL – "GENDER AFFIRMING" USES OF THE RELEVANT HORMONAL MEDICATIONS ARE NOT APPROVED BY THE FDA: Gender identity is consolidated during puberty and adolescence as young people's bodies become more sexually differentiated and mature. How this normally happens is not well understood, so it is imperative to be cautious about interfering with this complex natural process. Far from being cautious and prudent in using puberty blockers to treat gender dysphoria, too many providers engaged in gender affirming medical interventions are conducting an unethical and risky experiment that does not come close to the ethical standards demanded in other areas of medicine. No one really knows all

the potential consequences of puberty blocking as a treatment for gender dysphoria, but there are some known effects of pubertal suppression on children who are physiologically normal, and these carry long-term health risks. Children placed on puberty blockers have slower rates of growth in height, and an elevated risk of low bone-mineral density. Another possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation. (See, Arain, M., Haque, M., Johal, L., Mathur, P., Nel, W., Rais, A., Sandhu, R., & Sharma, S. (2013). Maturation adolescent brain. Neuropsychiatric disease and treatment, 449–461. When followed by cross-sex hormones, known and https://doi.org/10.2147/NDT.S39776). potential effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease. Tragically, those children who persist in their transgender identity and take puberty blockers and cross-sex hormones are *expected to become sterile*. Given what we already know about puberty blocking and how much remains unknown, it is not surprising that the use of GnRH analogues for puberty suppression in children with gender dysphoria is not FDA-approved. The off-label prescription of these drugs is legal but unethical outside the setting of a carefully controlled and supervised clinical trial. See, Hruz, Mayer, and McHugh, "Growing Pains." Trans activist professionals act as if there is a firm scientific consensus that it is safe and effective to treat gender dysphoria by using GnRH analogues to suppress normal puberty indefinitely. But this is far from the reality, as I, together with Mayer and McHugh, have pointed out: "Whether puberty suppression is safe and effective when used for gender dysphoria remains unclear and unsupported by rigorous scientific evidence." Thus, is not generally accepted by the relevant scientific community. Instead of regarding puberty blocking as a "prudent and scientifically proven treatment option," courts of law, parents, and the medical community should view it as a "drastic and experimental measure."

(See, Hruz, Mayer, and McHugh, 2017) The use of any experimental medical treatment on children calls for "especially intense scrutiny, since children cannot provide proper legal consent to experimental medical treatments — especially treatments that may harm natural gender **processes and produce sterility.** The rapid acceptance of puberty suppression as a treatment for gender dysphoria with little scientific support or scrutiny should raise concerns about the welfare of the children who receive such treatments. In particular, we should question the claim that it is both physiologically and psychologically "reversible." This includes the alteration of a temporally dependent developmental process. After an extended period of pubertal suppression one cannot "turn back the clock" and reverse changes in the normal coordinated pattern of adolescent psychological development and puberty (See, Hruz, Mayer, and McHugh, "Growing Pains, The New Atlantis: A Journal of Technology and Society, Spring 2017, pg 3-36.) See, also Vijayakumar N, Op de Macks Z, Shirtcliff EA, Pfeifer JH. Puberty and the human brain: Insights into adolescent development. Neurosci Biobehav Rev. 2018 Sep;92:417-436. doi: 10.1016/j.neubiorev.2018.06.004. Epub 2018 Jul 1. PMID: 29972766; PMCID: PMC6234123.; See also, Choudhury S, Culturing the adolescent brain: what can neuroscience learn from anthropology?, Social Cognitive and Affective Neuroscience, Volume 5, Issue 2-3, June/September 2010, Pages 159–167, https://doi.org/10.1093/scan/nsp030

64. "CANCEL CULTURE" POLITICAL-ACTIVIST ATTEMPTS TO CONTROL THIS DEBATE ARE HARMFUL TO SCIENCE: The controversies regarding the risks and potential dangers of the transgender industry cannot be silenced by "cancel culture". As Steven Levine, MD of Case Western has noted, "Among psychiatrists and psychotherapists who practice in the area, there are currently widely varying views concerning both the causes of, and appropriate therapeutic responses to, gender dysphoria in children. Dr Levine went on to state, "Existing"

studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals." Although political advocates have asserted that the "affirmation therapy" model is accepted and agreed with by the overwhelming majority of mental health professionals, many respected academics and providers in the field strongly disagree. For example, J. Cantor, Ph.D. (McGill) published the following opinion in 2019, "almost all clinics and professional associations in the world" do NOT use "gender affirmation" for prepubescent children and instead "delay any transitions until after the onset of puberty." See, "J. Cantor (2019), Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, J. of Sex& Marital Therapy, 1, DOI: 10.1080.0092623X.2019.1698481.

65. "CANCEL CULTURE" POLITICAL-ACTIVIST ATTEMPTS TO CONTROL THIS DEBATE ARE HARMFUL TO SCIENCE – NOTE THE ATTACKS ON DR RYAN'S BOOK:

In the midst of this ongoing international, raging controversy, transgender and allied political activists have attempted to silence open public debate on the risks and benefits of transgender medical procedures and political ideologies. For example, Ryan Anderson, Ph.D. a policy analyst wrote a book analyzing the scientific and policy issues involved in assessing the risks and benefits of the current practices of the Transgender Treatment Industry. See, Anderson, R., When Harry Became Sally: Responding to the Transgender Moment, Encounter Books. Despite widespread scientific interest and positive reviews, the book was banned from sale by the Amazon Corporation. Too many lives are at stake for such blatant suppression of open scientific discussion. Several positive reviews of Dr Ryan's book were posted by notable members of the relevant scientific-ethical community including: Paul McHugh, MD, University Distinguished Professor of Psychiatry, Johns Hopkins University School of Medicine. (Dr McHugh was trained

at Harvard College and Harvard Medical School. He served as the Chairman of Psychiatry at Johns Hopkins Medical School for decades) and Melissa Moschella, PhD, who served at Columbia University as Director of the Center for Biomedical Ethics in the Department of Medicine and currently at The Catholic University of America. (Dr. Moschella was trained at Harvard College and her PhD is from Princeton University) and Maureen Condic, Associate Professor of Neurobiology and Adjunct Professor of Pediatrics, University of Utah Medical School. (Dr. Condic's training includes a B.A. from the University of Chicago, and a Ph.D. from the University of California, Berkeley) and John Finnes, Ph.D., Professor of Law at Oxford University for 40 years, now Emeritus. (LL.B. from Adelaide University (Australia) and Ph.D. in 1965 from Oxford University as a Rhodes Scholar at University College Oxford.)

International experts from a variety of relevant science - legal - ethical fields consider the issue of proper and harmful transgender treatments *to be a serious controversy that must not be silenced*. Other scholars in this contentious field have been threatened and/or silenced by the political and ideological allies of the Gender Transition Industry. Consider, for example, the case of Alan Josephson, MD, a distinguished psychiatrist. In the fall of 2017 Dr Josephson appeared on an off campus panel symposium — not affiliated with his university — at the Heritage Foundation and shared his scientific, professional opinions on the experimental medicalization of gender dysphoric youth. The university responded by demoting him and then effectively firing him. Professor Josephson has filed a federal lawsuit to protect this academic rights to free speech. (See, Josephson v. Bendapudi, filed in the U.S. District Court for the Western District of Kentucky). The ongoing attempts to ban books and aggressively silence academic debate or "cancel" professionals with alternative views are clear demonstrations of the ongoing and intense controversies surrounding the Gender Transition Industry. See, Kearns, M., Gender Dissenter Gets

Fired, Jan 12, 2019. "Allan M. Josephson is a distinguished psychiatrist who, since 2003, has transformed the division of child and adolescent psychiatry and psychology at the University of Louisville from a struggling department to a nationally acclaimed program. In the fall of 2017 he appeared on a panel at the Heritage Foundation and shared his professional opinion on the medicalization of gender-confused youth. The university responded by demoting him and then effectively firing him.". Theories in the midst of an international firestorm of controversy are clearly not "generally accepted" by the relevant scientific community.

66. "CANCEL CULTURE" POLITICAL-ACTIVIST ATTEMPTS TO CONTROL THIS DEBATE ARE HARMFUL TO SCIENCE – E.G., ATTACKS ON DR LITTMAN'S RESEARCH:

Consider also the example of Dr. Lisa Littman at Brown University. Lisa Littman, M.D., MPA was a researcher at Brown University Medical School. Dr. Littman conducted extensive surveys to assess the experiences of parents involved in an online community for parents of transgender children or "gender skeptical" parents and children. There were 256 completed surveys. Their children were mostly adolescents or young adults. The parents reported that about 80 percent of their (mostly adolescent) children announced their transgender identity "out of the blue" without the long-term history generally associated with gender dysphoria. The parents also reported that transgender identity was linked with mental health issues (an often repeated, reliable finding in multiple studies from multiple nations). The parents also reported that their children's mental health worsened after they came out as transgender as did relationships with family members. The parents also reported a *decline* in the children's social adjustment after the announcement (e.g. more isolation, more distrust of non-transgender information sources, etc.).

The publication of the Littman paper was greeted by the outrage of trans activists who denounced the paper and Dr. Littman, calling it "hate speech and transphobic". Brown University had initially produced a press release for the paper stating the Littman research provided bold new insights into transgender issues. Once the political attacks began, the university, removed it from their announcements. Fortunately, in this case, there was also a counter-outcry from scientists, decrying Brown University and the political activists for threatening academic freedom and censoring scientific research that might assist in the treatment of gender dysphoria.

There was also reportedly an academic petition signed by members of the relevant scientific community. For example, Lee Jussim, PhD., Chair of the Psychology Department at Rutgers University wrote, "If the Littman study is wrong, let someone produce evidence that it is wrong. Until that time, if the research p*sses some people off, who cares? Galileo and Darwin p*ssed people off too. Brown University should be ashamed of itself for caving to sociopolitical pressure. Science denial, anyone?" Similarly, Richard B. Krueger, MD (a Harvard Medical School graduate) of Columbia University College of Physicians and Surgeons, board certified psychiatrist specializing in the treatment of sexual disorders wrote, "Brown University's actions in its failure to support Dr. Littman's peer reviewed research are abhorrent". Similarly, Nicholas Wolfinger, PhD (UC Berkeley, UCLA), currently Professor of Family and Consumer Studies at the University of Utah wrote: "The well-being of trans youth and other sexual minorities is best served by more research, not less".

The onslaught of attacks resulted in the journal asking Dr. Littman to publish a "corrected" version of the paper. After careful review, the paper was again published with additional information but no methodological nor data corrections – as no such errors were found. See, https://www.psychologytoday.com/us/blog/rabble-rouser/201903/rapid-onset-gender-dysphoria.

See also, Littman, L., Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, PLOS ONE March 19, 2019, https://doi.org/10.1371/journal.pone.0214157. Dr. Littman's paper was a key initial step in the alternative investigative hypothesis that the very recent and enormous increase in teenage girls seeking "gender transitioning" is due to a social contagion process at school, in peer groups, and on the internet. This theory has yet to be tested in detail.

67. UNDERLYING PATIENT BIOLOGY IS NOT CHANGED BY ALTERING BODILY FEATURES TO "PASS" AS THE OPPOSITE SEX NOR DO SUCH ALTERATIONS CHANGE BIOLOGICAL DISEASE VULNERABILITIES ASSOCIATED WITH GENETICALLY-DEFINED SEX: Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by genetic makeup, normatively by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex. (See "Institute of Medicine (US) Committee on Understanding the Biology of Sex and Gender Differences. Exploring the Biological Contributions to Human Health: Does Sex Matter?" Wizemann TM, Pardue ML, editors. Washington (DC): National Academies Press (US); 2001. PMID: 25057540.) For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the individual with sex-discordant gender identity to become "a complete man" or "a complete woman," this is not biologically attainable. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks, as I

detail later. See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex & Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ("Informed Consent"); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. Am. Acad Psychiatry Law 44, 236 at 238 ("Reflections").

68. INVESTIGATING ALTERNATIVE HYPOTHESES: THE SOCIAL CONTAGION THEORY: ONE OF THE MOST CONTROVERSIAL AND CONTENTIOUS ISSUES IN TRANSGENDER SCIENCE IS THE RECENT EPIDEMIC OF ADOLESCENT FEMALE TO MALE GENDER DISCORDANT PATIENTS:

How prevalent is the Sudden Onset Gender Dysphoria Epidemic in Teen Girls first described by the research of Dr Littman at Brown University?

In Great Britain, centralized medical care provides data to track health care phenomenon ... the number of adolescent girls seeking sex transitioning exploded over FOUR THOUSAND 4,000% in the last decade. Similarly, in America, where we lack the same kinds of centralized health care data, it has been reported that in 2018 2% (2 in 100) of high school students identified on surveys as "transgender" — this is 200 times greater response — a 20,000% increase — over reports during past decades which showed a rate of only .01 percent (one in 10,000 people). See, Johns MM, Lowry R, Andrzejewski J, et al. Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students — 19 States and Large Urban School Districts, 2017. MMWR Morb Mortal Wkly Rep 2019;68:67–71.

Along with this increase in transgender patients and identifiers, has come *a radical and* recent transformation of the patient population from early onset males to rapid onset adolescent girls. Thus currently the majority of new patients with sex-gender discordance are not males with

a long, stable history of gender dysphoria since early childhood —as they were for decades — but instead adolescent females with no documented long-term history of gender dysphoria — thus they experienced "rapid onset" transgender identification. Whole groups of female friends in colleges, high schools, and even middle schools across the country are reportedly coming out together in peer group clusters as "transgender." These are girls who — by detailed parental reports and self-reports — had never experienced any discomfort in their biological sex until they heard a coming-out story from a speaker at a school assembly or discovered the internet (YouTube) community of trans "influencer video stars."

This extraordinary change in new patient demographics appears more consistent with a theory of social contagion than of "immutable identification", "brain structures", "genetics", or other biological hypotheses. Many unsuspecting parents, whose children have never shown any signs for gender discordant feelings or ideas, are awakening to find their daughters in thrall to hip trans YouTube stars and "gender-affirming" educators and activist therapists who push life-changing interventions on these young girls—including double mastectomies and hormonal puberty blockers that can potentially cause permanent infertility. See, Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS One. 2018 Aug 16;13(8):e0202330. doi: 10.1371/journal.pone.0202330. Erratum in: PLoS One. 2019 Mar 19;14(3):e0214157. PMID: 30114286; PMCID: PMC6095578.

69. EXPLORING ALTERNATIVE HYPOTHESES: WHY ARE WE SEEING A RAPID RISE OF ADOLESCENT FEMALE TRANS IDENTITY PATIENTS... often in social clusters? Generating, Considering, and Testing Alternative Theories prevents the Methodological Error of Confirmation Bias:

We should consider the genetics theory of transgender identity. But his theory cannot explain the rapid expansion of new GD (an 4,000% to 20,000% increase?) cases as our genome is simply not changing that fast.

We should consider the "brain structures" theory of transgender identity. Yet there is only weak medical evidence to support this theory and the theory cannot explain the rapid expansion of new gender dysphoria cases as brain structures are not changing that fast.

We should consider the theory that increased social acceptance of the transgender lifestyle is leading many people who were transgender all along to come out. Yet this theory fails to explain why *males and older women are not coming out in the same huge numbers* and not coming out in "social peer group clusters" as adolescent females are reportedly doing.

We should consider the "immutable gender identity" theory. Yet this theory fails to explain the rapid expansion of patients. In addition, the "immutable" theory fails to explain the rapid expansion of "Rapid Onset Gender Dysphoria" reports — newly "trans" adolescent girl patients who reportedly showed no indication of gender dysphoria previously.

Having considered alternative theories -- to avoid confirmation bias – it appears that another alternative theory might well be the most applicable, rational theory to explain the extreme, recent increases in the GD patient population. This is the Social Contagion hypothesis. Social contagion effects are also reportedly responsible for the massive, rapid increase in "recovered repressed memory" cases and also the extraordinary expansion of "multiple personality disorder" cases in the 1990s. I also note the alternative investigative hypothesis that *social contagion effects would appear to be psychological/psychiatric problems and NOT physical medical problems requiring hormonal or surgical "treatments"*.

70. INVESTIGATING ALTERNATIVE HYPOTHESES: THE SOCIAL CONTAGION THEORY: ADOLESCENT FEMALE PSYCHOLOGY RESEARCH SHOWS WELL-DOCUMENTED PEER INFLUENCES on ANOREXIA, BULIMIA, DRUG ABUSE, and now GENDER DISCORDANT ("TRANSGENDER") SYMPTOMS:

The Social Contagion theory for the large increase in reported Rapid Onset Gender Dysphoria in adolescent girls appears to be the most rational explanation for the reportedly dramatic (rapid, media related, hundreds of times increase, YouTube influenced, Peer Group influenced) explosion of Gender Discordant ("transgender") patients among adolescent female friend groups.

Adolescent female social contagion effects in psychiatric illness are well-known and well documented. Consider, for example, Bulimia and Anorexia — both of which spread rapidly in adolescent female friend groups. See, Allison S, Warin M, Bastiampillai T. Anorexia nervosa and social contagion: clinical implications. Aust N Z J Psychiatry. 2014 Feb;48(2):116-20. doi: 10.1177/0004867413502092. Epub 2013 Aug 22. PMID: 23969627.

It has been known for decades that adolescent females are highly prone to social contagion effects spreading psychiatric symptoms — e.g. Anorexia, Bulimia, Drug Abuse, etc) are well known to be subject to "cluster" and "friendship" contagions as teens girls (and especially troubled teen girls) co-ruminate and share feelings at very high rates and with emotional depth. See, e.g., Crandall CS. Social contagion of binge eating. J Pers Soc Psychol. 1988 Oct;55(4):588-98. doi: 10.1037//0022-3514.55.4.588. PMID: 3193348.

For example, Prof. Amanda Rose at the University of Missouri has conducted research to understand why adolescent girls show such susceptibility to social contagion with psychiatric symptoms — "Teenage girls share symptoms via social contagions because their friendship

processes involve "co-rumination", that is, taking on the emotional pain and concerns of their friends." See, R. Schwatz-Mette and A. Rose, Co-Rumination Mediates Contagion of Internalizing Symptoms Within Youths 'Friendships, Developmental Psychology 48(5):1355-65, February 2012, DOI: 10.1037/a0027484 Developmental Psychology, Vol. 48, No. 5, 1355–1365 0012-1649/12/\$12.00 DOI: 10.1037/a0027484. This could be one explanation for why we are hearing increasing reports of "clusters" and "friend groups" of teen girls who are adopting a "transgender identity" and "transitioning" as friends together.

71. INVESTIGATING ALTERNATIVE HYPOTHESES: THE SOCIAL CONTAGION THEORY: SCHOOL ENVIRONMENT SOCIAL CONTAGION: Observers including journalists have reported that schools in America — 1st grade through College — during the past few years have been aggressively teaching that a "non-binary" identity is the real "norm" and far better than traditional gender roles. Such school programs present Male and Female roles in a very rigid, highly stereotyped manner then teach children (even 1st graders) that if they do or feel anything different than narrow binary sex roles (girls enjoying football, boys enjoying art) they are surely "non-binary" and should receive much social support, reinforcement, and encouragement for "transitioning".

The rapid and historic transformation of the Gender Transition Industry patient pool has been widely noted by researchers, journalists, and providers. This transformation from early onset, chronically dysphoric male patients to rapid onset adolescent female patients has occurred in just the last few years. The patient transformation from 3 to 1 males (for decades) to 7 to 1 females (just in the last few years) is not easily explained by any of the Gender Transition Industry theories such as "genetics" or "brain structures" or the mysterious and tautalogical "immutable characteristics" theory. It has been reported that during this enormous increase in "Rapid Onset

Gender Dysphoria" a growing set of YouTube Transgender "influencers" teach and entertain millions of followers daily as they aggressively sell gender transitioning as a quick and effective cure for Depression, Anxiety, Loneliness, and confusion about life.

For example, journalist Abigail Shrier's book, *Irreversible Damage* about the social contagion theory of why patient demographics changed so very rapidly and expansively. Shrier's book was reportedly named a "Book of the Year" by The Economist and "one the Best Books of 2021" by The Times (of London) and The Sunday Times (of London). Many famed scientists of various fields have praised Shrier's work in highlighting A) the lack of competent scientific research supporting "gender affirmation" interventions and B) the political contamination including censorship and "cancel culture" attacks on academics that make gender affirmation investigation ("transgender science") such a controversial field. For example, several highly credible and deeply respected members of the relevant scientific and public policy-ethics communities have reportedly posted positive reviews of Shrier's analysis on the Amazon bookseller site including:

"In *Irreversible Damage*, Abigail Shrier provides a thought-provoking examination of a new clinical phenomenon mainly affecting adolescent females—what some have termed rapid-onset gender dysphoria—that has, at lightning speed, swept across North America and parts of Western Europe and Scandinavia. In so doing, Shrier does not shy away from the politics that pervade the field of gender dysphoria. It is a book that will be of great interest to parents, the general public, and mental health clinicians."— Kenneth J. Zucker, Ph.D., adolescent and child psychologist, multi-publication scientist in this field, and *Chair* of the American Psychiatric Association DSM-5 Work Group on Sexual and Gender Identity Disorders.

Similarly, "Abigail Shrier's book is thoroughly researched and beautifully written." —**Ray Blanchard, Ph.D.,** head of Clinical Sexology Services at the Centre for Addiction and Mental Health from 1995–2010.

Similarly, "For no other topic have science and conventional wisdom changed—been thrown away—more rapidly than for gender dysphoria. For a small but rapidly growing number of adolescent girls and their families, consequences have been tragic. This urgently needed book is fascinating, wrenching, and wise. Unlike so many of the currently woke, Abigail Shrier sees clearly what is in front of our faces and is brave enough to name it. Irreversible Damage will be a rallying point to reversing the damage being done." —J. Michael Bailey, Ph.D. professor of psychology at Northwestern University. All quotes from the Amazon bookseller site at https://www.amazon.com/Irreversible-Damage-Transgender-Seducing-

<u>Daughters/dp/1684510317</u> These quotes are offered to demonstrate the breadth and depth and international scope of the raging controversies regarding the Transgender Treatment Industry.

72. THE SOCIAL CONTAGION HYPOTHESIS - IDENTITY POLITICAL IDEOLOGY PROVIDES SOCIAL SUPPORT REWARDS FOR ADOLESCENTS TO ADOPT A GENDER DISCORDANT IDENTIFY ("TRANSGENDER"): Journalists have reported, "In many high schools, there is an "identity politics" victims sweepstakes where white middle and upper middle class girls are simply left out of any coveted "oppressed victim" status groups — thus the decision to become "transgender" brings instant social support and acclaim from teachers and coaches for their courage in coming out." Nobody questions such personal transformation, even if the teen is deeply troubled, and even if the teen has no history of gender dysphoria. To even ask questions or explore alternative explanations could get the teacher, counselor, therapist, or physician labelled as a "conversion therapist" and cancelled.

73. ALTERNATIVE INVESTIGATIONAL HYPOTHESES: "CANCEL CULTURE" and IDEOLOGICAL-POLITICAL PRESSURE SEEKS TO INSTITUTIONALIZE THE SYSTEMATIC NEGLIGENCE and METHODOLOGICAL ERROR OF CONFIRMATION BIAS: Because of the efforts of apparently science illiterate and/or gullible legal and medical professionals and the intense activity of political trans activists — health providers (in many fields) are now NOT permitted to openly asks questions, properly investigate alternative diagnoses, or explore alternative hypotheses for the symptoms of Gender Dysphoria patients. They are compelled (sometimes under fear of employment termination or legal attacks) to adopt a patient's self-diagnosis and only support "transgender affirming" medical interventions. These providers are thus being pressured and/or compelled to commit the scientific and medical malpractice of Confirmation Bias. (See, detailed discussion above on confirmation bias.) Unexamined transgender affirming medical interventions — based on uncorroborated patient selfreports, assessed by mental health professionals with no methodology for discerning true from false patient reports, with no ability to decipher accurate from contaminated "memories", with no alternative treatments offered, and no alternative explanations (social contagion) explored may thus be viewed as engaged in medical, psychological, surgical, and endocrinological negligence and a violation of the most basic, essential scientific and medical practices and methods requiring the generation and testing of alternative hypotheses. In sum, such a politically tainted system actually requires "confirmation bias" — one of the most serious of all methodological diagnostic failures. See, e.g. Mendel, R. et. al., Confirmation bias: why psychiatrists stick to wrong preliminary diagnoses, Psychological Medicine, Oxford University Press, 20 May 2011. ["Diagnostic errors can have tremendous consequences because they can result in a fatal chain of wrong decisions. Experts assume that physicians' desire to confirm a preliminary diagnosis while failing to seek contradictory evidence is an important reason for wrong diagnoses. This tendency is called 'confirmation bias']; See also, Doherty, T.S. and Carroll, A.E., Believing in Overcoming Cognitive Biases, American Medical Association Journal of Ethics, 2020;22(9):E773-778. ["Like all humans, health professionals are subject to cognitive biases that can render diagnoses and treatment decisions vulnerable to error. Learning effective debiasing strategies and cultivating awareness of confirmation, anchoring, and outcomes biases and the affect heuristic, among others, and their effects on clinical decision making should be prioritized in all stages of medical education.... Confirmation bias is the selective gathering and interpretation of evidence consistent with current beliefs and the neglect of evidence that contradicts them....]; See also, Hershberger PJ, Part HM, Markert RJ, Cohen SM, Finger WW. Teaching awareness of cognitive bias in medical decision making. Acad Med. 1995;70(8):661.

74. ALTERNATIVE INVESTIGATIONAL HYPOTHESES: GIVEN THE CURRENT LACK OF RELIABLE-VALID RESEARCH SUPPORT, IT IS A RECKLESS and EXPERIMENTAL INTERVENTION TO PERMIT CHILDREN TO ENGAGE IN SELF-DIAGNOSIS WHEN THE RESULTING "TREATMENTS" WILL LIKELY PRODUCE LIFE-LONG STERILIZATION and/or OTHER PERMANANT INJURIES TO NORMAL, HEALTHY ORGANS: In some jurisdictions in America now child or adolescent patients can — without parental permission or even parental notification -- receive hormones to begin the experimental treatment of "transitioning" with no competent diagnostic investigation or professional assessment of "Gender Dysphoria" and no competent medical investigation-testing-consideration of alternative hypotheses (there is no such reliable, objective assessment). Worst of all, providers can be coerced by law, collegial pressures, or "cancel culture" ideology to comply with the troubled child's/teen's/patient's amateur (potentially YouTube influenced) self-diagnosis or be faced with

potentially career ending allegations of "conversion therapy". Politically tainted, pseudo-science, experimental, unproven medical practices have caused grave harm to millions in the past (See the discussion of lobotomies, repressed memory therapy, multiple personality therapy, rebirthing therapy, etc above.) and unethical, politically driven, experimental medical errors should not be repeated today.

- 75. EXPERIMENTATION on SEX-GENDER DISCORDANT PATIENTS IS ESPECIALLY LIKELY TO CAUSE HARM TO MINORITY PATIENTS FROM HISTORICALLY MARGINALIZED COMMUNITIES The development of effective strategies to impact long-term physical and psychological health in patients who experience sex-discordant gender identity should be undertaken with recognition of the disproportionate burden of this condition in a number of vulnerable minority populations of children. These include:
- -- children with a prior history of psychiatric illness (See, e.g. Kaltiala-Heino, R., Sumia, M., Työläjärvi, M., & Lindberg, N. (2015). Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child and adolescent psychiatry and mental health*, *9*, 9. https://doi.org/10.1186/s13034-015-0042-y
- -- children of color (See, e.g., G. Rider et al. (2018), Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study, Pediatrics at 4, DOI: 10.1542/peds.2017-1683.
- -- children with mental developmental disabilities (See, e.g. Bedard, C., Zhang, H.L. & Zucker, K.J. Gender Identity and Sexual Orientation in People with Developmental Disabilities. *Sex Disabil* **28**, 165–175 (2010). https://doi.org/10.1007/s11195-010-9155-7
- children on the autistic spectrum (See, e.g., de Vries, A. L., Noens, I. L., Cohen-Kettenis, P. T., van Berckelaer-Onnes, I. A. & Doreleijers, T. A. Autism spectrum disorders in gender

dysphoric children and adolescents. *J Autism Dev Disord* **40**, 930-936, doi:10.1007/s10803-010-0935-9 (2010).

-- children residing in foster care homes and adopted children (See, e.g. See e.g., D. Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, Transgender Health Vol. 2(1).

76. GENDER DYSPHORIA IS A VERY RARE PSYCHIATRIC CONDITION – THAT IS, RARE IN THAT IT IS TREATED WITH SURGERY THAT DAMAGES or DESTROYS WELL-FUNCTIONING, HEALTHY BODILY ORGANS LEADING TO LOSS OF ESSENTIAL BODILY FUNCTIONS (e.g. Medically Induced Sterilization): Despite the fact that gender dysphoria represents a psychological condition (as catalogued in the DSM since the third edition of this publication), some conceptualize the condition as a medical illness similar to cancer. When considered from this viewpoint, the goal of "treatment" is to alter the appearance of the body to conform to a patient's perceived sexual identity, including the physical removal of unwanted "diseased" sexual organs. Since undesired body parts are fully formed and functional prior to hormonal or surgical intervention, the result of these "therapies" is injury to innate sexual ability. In particular, loss or alteration of primary sexual organs leads directly to impairment of reproductive potential. Recognition of this obvious consequence is the basis for the development of new arenas of medical practice where there is an attempt to restore what has been intentionally destroyed. See, e.g., Ainsworth AJ, Allyse M, Khan Z. Fertility Preservation for Transgender Individuals: Review. Mayo Clin 95(4):784-792. Proc. 2020 Apr; 10.1016/j.mayocp.2019.10.040. Epub 2020 Feb 27. PMID: 32115195. As correctly noted by Levine, gender dysphoria is unique in that it is "the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified

biological abnormality". See, e.g., S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law, 44, 236 at 238 ("Reflections"), at 240.)

77. A MULTI-DISCIPLINARY, COMPLEX, DEVELOPMENTAL MODEL PROVIDES ESSENTIAL ALTERNATIVE HYPOTHESES TO THE SIMPLE, UNEXAMINED "AFFIRMATON" TRANSITIONING MODEL OF TRANS ACTIVIST PROFESSIONALS and the GENDER TRANSTION INDUSTRY: The diagnosis of "gender dysphoria" encompasses a diverse array of conditions. While the etiologic contributors to sex discordant gender identity remain to be fully identified and characterized, differences both in kind and degree within individuals and across varied populations creates challenges in establishing specific approaches to alleviate associated suffering. For example, data from adults cannot be assumed to apply equally to children. Nor can data from children who present with sex discordant gender pre-pubertally be presumed to apply to the growing number of post-pubertal adolescent females presenting with this condition. Steven Levine, MD (Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine and Founder and Co-Director of the Case Western Reserve University Gender Identity Clinic) has described the developmental model — an alternative hypothesis of gender dysphoria conceptualization and treatment that is more in keeping with the known science and involves reduced costs and lowered risk of permanent physical harm (e.g., medically induced sterilization) to patients. Dr. Levine has written, "Gender dysphoria can be alternatively conceptualized in developmental terms, as an adaptation to a psychological problem that was first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (See, e.g., S. Levine (2016),

Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law 44, 236 at 238). Mental Health Professionals (MHPs) who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self, and also to ameliorate suffering when the underlying problem cannot be solved. They work with the patient and (ideally) family to inquire what forces may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play." (See, Expert Report by Steven Levine, MD). A recent study documented "clustering" of new presentations in specific schools and among specific friend (peer) groups, pointing to social influences (See, the Littman study at Brown University discussed above). Both of these findings strongly suggest cultural factors. From the beginning of epidemiological research into this arena, there have always been some countries, Poland and Australia, for example, where the patient sex ratios were reversed as compared to North America and Europe, again demonstrating a powerful effect of cultural influences (e.g. social contagion). See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex & Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885; S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy Psychiatry and Law, 44, 236 at 238.

78. NO COMPETENT, SCIENTIFICALLY VALID-RELIABLE COST-BENEFIT ANALYSIS HAS BEEN DONE ON GENDER DISCORDANT "TRANSGENDER" TREATMENTS — When the FDA tests a drug, the safety analysis looks at all related risks. Specifically, the drug (treatment) must not only be effective, but it must not cause side effects that are more damaging than the proposed treatment. This is one of the key weaknesses of the Gender

Transition Industry. Not only have the treatments NOT been proven reliably effective compared in NO treatment, but the "transgender transitioning" interventions "treatments" are *DESIGNED* with existing knowledge of well-documented, long-term health problems and damages (e.g., testosterone use by transgender men increases the risk of fatal heart disease, estrogen use by transgender women increases risk of blood clots and strokes, Gender Transition Industry treatments — if completed — can cause life-long sterility, etc.).

- 79. LACK OF INTEGRATION OF CARE BY PROVIDERS IN THE GENDER TRANSITION INDUSTRY INCREASES DANGERS TO PATIENTS: It is too often the case in the Gender Transition Industry that "nobody is in charge" of a patient's care. The mental health professionals know little about the risks of surgery and the surgeons know little about the defects in mental health methodologies and the endocrinologists are only following the hormonal treatments and many are not aware of the serious methodological research defects in this field. Such disjointed care can increase dangers to patients. On cases showing such a lack of integration and uncertain chain of command in Gender Transition Industry healthcare cases, reliable measurements of the divergent, multi-disciplinary risks to patients of Gender Transition Industry treatments (e.g. hormones, incomplete therapy, or surgical side effects) are precluded and too often ignored. The Plaintiffs' expert witness reports in this case appear to ignore this issue.
- 80. ADDITIONAL OPINIONS TO BE DISCUSSED AT DEPOSITION OR TRIAL: There are additional relevant data and important considerations regarding existing understanding of the role of physicians and other healthcare workers in alleviating suffering in patients who experience gender dysphoria due to sex-gender identity discordance that are not fully discussed in this report. This includes:

- -- the inherent complexity of human psychological and physical development from birth to adulthood
 - -- the relationship and differences between puberty and adolescence
 - -- the molecular mechanisms of steroid hormone action in regulating cellular gene expression
- -- the physiology of sexual function including the hypothalamic-pituitary-gonadal axis in males and females and diseases that are associated with dysfunction of these processes
- -- the expansive and growing field of sex-specific personalized medicine in relation to human health
- -- the historical development and use of the scientific method (e.g. principles of hypothesis generation, testing of the null hypothesis, fundamentals of statistical analyses, differences between statistical and clinical significance)
 - -- the design and conduct of human clinical trials
- -- the proper role of institutional review boards in the approval and supervision of clinical trials to mitigate risk
- -- the National Institutes of Health (NIH) processes for establishment of research priorities (e.g. research funding announcements), procedures for scientists to apply for grant funding, peer review of research proposals, requirements for examining sex as a biological variable, safety monitoring, and requirements for sharing study results
- -- the process for gaining FDA approval for new medications and new medical indications for existing medications including objective assessment of relative risk versus benefit as demonstrated from properly controlled clinical trials

These topics will be discussed, as needed, at deposition and trial to provide the court with the necessary scientific and medical information for proper litigation of this case. 81. NOTES: GENDER TRANSITION RESEARCH SHOWING METHODOLOGICAL DEFECTS, ERRORS, and the UNETHICAL MISREPORTING OF RESULTS.

In sum, THE GENDER TRANSITION INDUSTRY APPEARS TO HAVE IMPLODED IN RECENT YEARS as the relevant scientific community exposed the serious methodological and ethical errors in this highly controversial industry.

DR HRUZ'S NOTES ON RESEARCH EVALUATIONS and METHODOLOGICAL ANALYSES:

TIMELINE NOTES DOCUMENT THE LOW QUALITY EVIDENCE FOR THE GENDER TRANSITION INDUSTRY'S EXPERIMENTAL TREATMENTS FOR DECADES FOLLOWED BY THE PUBLIC EXPOSURE of DEFECTS and MISCONDUCT and IMPLOSION OF THE GENDER TRANSITION INDUSTRY IN 2020-2021:

- 2016 OLSON-KENNEDY ET AL "CLINICALLY USEFUL TO PREDICT OUTCOMES IS LACKING" ... "EXTENSIVE RESEARCH IS NEEDED" ... GROSS METHODOLOGICAL DEFECTS IN "TRANSGENDER" RESEARCH ARE BEING EXPOSED See, GROSS METHODOLOGICAL DEFECTS IN "TRANSGENDER" RESEARCH HAVE BEEN EXPOSED IN PUBLIC VENUES Olson-Kennedy, J, et. al. listed a number of the serious defects in our current understanding of transgender patients. She noted:
- —" Clinically useful information for predicting individual psychosexual development pathways is lacking." [Note: We can't predict outcomes because we don't understand the processes thus "affirming" treatments are experimental].
- "Transgender youth are at high risk for poor medical and psychosocial outcomes." [Note: But we don't know why] ...
- "Longitudinal data examining the impact of early social transition and medical interventions *are sparse.*" [Note: Thus we don't know how to treat such patients.]
- "Existing tools to understand gender identity and quantify gender dysphoria *need to be reconfigured* to study a more diverse cohort of transgender individuals." [Note: For decades patients were uniformly males with early childhood onset, now most new patients are females with rapid onset in adolescence —are these even the same patient groups?].

Shared goals *requiring much more research*: "Extensive research is needed to improve understanding of gender dysphoria, and transgender experience, particularly among youth. Recommendations include identification of predictors of persistence of gender dysphoria from childhood into adolescence [the key research hasn't been done yet], and a thorough investigation into the impact of interventions for transgender youth. [the key research hasn't been done yet] Finally, *examining the social environments of transgender youth is critical for the development of appropriate interventions necessary to improve the lives of transgender people*. [This kind of multi-disciplinary research, analysis of alternative hypotheses, and treatments for concomitant psychiatric-psychological symptoms is being tragically mislabeled and blocked as "conversion therapy" by political advocates.]

 methodologically sound scientific support for the still-experimental gender affirmation "trans" interventions and the many unresearched missing questions in our understanding of these complex patients to Dr Brown's and Dr Schechter's misleading and incomplete expert declarations for the plaintiffs in this case.]

2016 - See, Marshall E, Claes L, Bouman WP, Witcomb GL, Arcelus J. Non-suicidal self-injury and suicidality in trans people: a systematic review of the literature. Int Rev Psychiatry 2016; 28: 58–69.) Activists and too many providers have used a fear of suicide to push experimental unproven treatments. Activists and too many providers have attempted to manipulate parents and patients with the fearful maxim 'better a live daughter than a dead son'. In addition, parents, teachers and doctors are encouraged to affirm unquestioningly the alternative gender for fear of the implied consequences. There is a danger that poor-quality data are being used to support gender affirmation and transition without the strength of evidence that would normally determine pathways of care. A 20-year Swedish longitudinal cohort study showed persisting high levels of psychiatric morbidity, suicidal acts and completed suicide many years AFTER medical transition. (See also, Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. Scott J, editor.) PLoS ONE 2011; 6(2): e16885. "Such results are not reassuring and might suggest that more complex (untreated) intrapsychic conflicts remain, unresolved by living as the opposite sex."

2017 - LONG TERM STUDIES OF GENDER TRANSITION TREATMENT EFFECTS SHOW PERSISTENT PSYCHOLOGICAL-PSYCHIATRIC MORBIDITY INCLUDING HIGHER RISK OF SERIOUS SUICIDE ATTEMPTS AFTER TRANSITIONING TREATMENTS: Evidence often cited to support societal measures that promote or encourage gender transition, including the Plaintiffs' demand for use of multi-user sex-segregated restrooms corresponding with the Plaintiffs' gender identity, as a medically necessary treatment for gender dysphoria is limited. Recent studies reporting reductions in dysphoria following social transition of adolescent patients are small, poorly controlled and of insufficient duration to draw definitive conclusions regarding long-term efficacy. Long-term follow up of patients with gender dysphoria who have undergone social and hormonal transition with or without surgical intervention has shown persistent psychological morbidity far above non-transgendered individuals with suicide attempts 7-fold and completed suicides19-fold above the general population - AFTER "transition" interventions. See, Adams, N., Hitomi, M. & Moody, C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health 2, 60-75, doi:10.1089/trgh.2016.0036 (2017); See also, Dhejne, C. et al. Long-term Follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011)).

2019 — SWEDEN NATIONAL REVIEW = GENDER AFFIRMATION STILL EXPERIMENTAL = NO RANDOMIZED TRIALS: results. See, Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019 (https://www.sbu.se/307e)

SWEDISH REVIEW —"<u>No relevant randomized controlled (treatment outcome) trials in</u> children and adolescents were found."

"This report was commissioned by the Swedish government and is a scoping review of the literature on gender dysphoria in children and adolescents. The report can be a basis for further evaluation of risk of bias and evidence.

Conclusions:

- We have <u>not found any scientific studies which explains the increase in incidence in children</u> and adolescents who seek the heath care because of gender dysphoria
- We have <u>not found any studies on changes in prevalence of gender dysphoria over calendar</u> time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria.

- There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.
- <u>Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium</u>.
- The scientific activity in the field seems high. A large part of the identified studies are published during 2018 and 2019.
- Almost all identified studies are observational, some with controls and some with evaluation before and after gender affirming treatment. <u>No relevant randomized controlled trials in children and adolescents were found.</u>

We have not found any composed national information from Sweden on: – the proportion of those who seek health care for gender dysphoria that get a formal diagnosis NOR – the proportion starting endocrine treatment to delay puberty NOR – the proportion starting gender affirming hormonal treatment NOR – the proportion subjected to different gender affirming surgery."

2016-2017 London GIDS Study

NO evidence that hormones or surgery improve long-term psychological well-being. See, "GIDS referrals figures for 2016/17, Gender Identity Development Service, GIDS.NHS.uk (undated), http://gids.nhs.uk/sites/default/files/content-uploads/referral-figures-2016-17.pdf

2017 - ENDOCRINE SOCIETY REVIEWS - ONLY <u>WEAK EVIDENCE</u> SUPPORTS GENDER TRANSITION INTERVENTIONS: Two systematic reviews commissioned by the US-based Endocrine Society in 2009 and 2017 concur with the finding of a <u>the weak evidence base</u>, stating that <u>the finding of benefits of hormonal interventions in terms of "psychological functioning and overall quality of life" <u>comes from "low-quality evidence</u> (i.e., which translates into <u>low confidence in the balance of risk and benefits</u>)."</u>

MISCONDUCT by the Endocrine Society: Despite this sober assessment, the Endocrine Society instructed clinicians to proceed with treating gender-dysphoric youth with hormonal interventions in its guidelines, which have now been broadly adopted by a number of medical societies. See, Transgender Health: An Endocrine Society Position Statement. December 15, 2020. Accessed January 6, 2021.https://www.endocrine.org/advocacy/position-statements/transgender-health

2017 - GENDER TRANSITION INTERVENTIONS REMAIN <u>EXPERIMENTAL</u> = The Society for Science Based Gender Medicine (SEGM)'s review, <u>the "low confidence in the balance of risks and benefits" of hormonal interventions calls for extreme caution</u> when working with gender-dysphoric youth, who are in the midst of a developmentally-appropriate phase of identity exploration and consolidation. While there may be short-term psychological benefits associated with the administration of hormonal interventions to youth, they must be weighed against the long-term risks to bone health, fertility, and other as yet-unknown risks of life-long hormonal supplementation.

Further, the irreversible nature of the effects of cross-sex hormones, and the potential for puberty blockers to alter the natural course of identity formation should give pause to all ethical clinicians. Studies consistently show that the vast majority of patients with childhood-onset gender distress who are not treated with "gender-affirmative" social transition or medical interventions grow up to be LGB adults. However, there is emerging evidence that socially-transitioned and puberty-suppressed children have much higher rates of persistence of transgender identification, necessitating future invasive and risky treatments. The trajectory of the novel, and currently the most common presentation of gender dysphoria, which emerges for the first time in adolescence following a gender-normative childhood is unknown, but the increasing voices of desisters and detransitioners suggest the rate of regret within this novel cohort will not be as rare as previously estimated.

It is The Society for Science Based Gender Medicine (SEGM)'s position that the significant uncertainties regarding the long-term risk/benefit profile of "gender-affirmative" hormonal

interventions call for noninvasive approaches (e.g. psychotherapy, social support, coping and resilience training, etc) as the first line of treatment for youth. If pursued, invasive and potentially irreversible interventions for youth should only be administered in clinical trial settings with rigorous study designs capable of determining whether these interventions are beneficial.

In addition to undergoing <u>rigorous psychological and psychiatric evaluations</u>, patients and their families should participate in a <u>valid informed consent process</u>. The latter must accurately disclose the limited prognostic ability of the gender dysphoria/gender incongruence diagnosis for young people, and <u>the many uncertainties regarding the long-term mental and physical health outcomes of these poorly studied and largely experimental interventions.</u>

See, Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, The Journal of Clinical Endocrinology & Metabolism, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643

2017 Misleading, politically motivated-tainted Cornell University website's alleged "systematic literature review" was actually a form of misleading consumer manipulation. See, Anonymous. Cornell University, Public Policy Research Portal. "What does the scholarly research say about the effect of gender transition on transgender well-being?" Available: https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/ [accessed 20 November 2019] The relevant scientific community reacted to expose misinformation in the Cornell "Review".

See, Horvath, Hacsi. (2020). Activist-driven transgender research methods are reckless and will "In 2017, anonymous authors at Cornell University lead to harms. 10.13140/RG.2.2.22455.55206. produced a document titled "What does the scholarly research say about the effect of gender transition on transgender well-being?". This document purports to be a "systematic literature review." In reality, it is simply a piece of "junk science", political propaganda, created by activists.... Horvath employed two instruments commonly used to assess the quality of systematic reviews. See, Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017 Sep. 21;358:j4008; and also Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097). ["The Cornell document fared poorly under examination with the AMSTAR 2 instrument. All questions answered with "No" or "Not reported" would optimally have been answered with 'Yes.' This review's methods appear to have been grossly inadequate.". The authors of the Cornell review failed to meet nearly every criterion of the PRISMA checklist. All items denoted as "Not done" would optimally have been answered 4 with "Done." Reporting of this review's methods and findings was very sloppy. Indeed, the review could hardly have been reported with less rigor]. Conclusions: The so-called "systematic literature review" produced at Cornell was nothing of the kind. Thus the "Findings" of this document should be ignored."

The public should be warned regarding this kind of material misrepresentation of potentially dangerous, experimental treatments of vulnerable patients.

2018 AMSTERDAM RESEARCH DEBACLE: Deceptive Claims and Research Errors in the 2018 Amsterdam Cohort Study Debacle of (2018)See, Wiepjes CM, Nota NM, de Blok CJ, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets. The Journal of Sexual Medicine 2018; 15(4): 582-90.

These authors deceptively claimed: "The percentage of people who regretted gonadectomy remained small and did not show a tendency to increase."

Noting research limitations, errors, and/or deceptions:

- "Not all data were available from the hospital registries, particularly older data or surgeries performed in other centers" (p.590)
- "A large number of transgender people...were lost to follow-up. Although transgender people receive lifelong care, a large group (36%) did not return to our clinic after several years of treatment" (page 589). (How many were suicides or detransitioning? The researchers did not assess and thus cannot report.)
- The "Regret" measure used was only tabulated for those who had gonadectomies <u>and ALSO</u> then requested hormone therapy consistent with biological sex "and ALSO expressed regret" (p.584); they also apparently *improperly excluded any patient who died* (are they hiding suicides?) (p.584)
- No uniform statistics were used to measure average follow-up time and variance = a **research** error increasing the unreliability of the data.

Admitted average time to regretting engaging in "transition" interventions was 130 months (10+YEARS). Page 589 admission: "...it <u>might be too early to examine regret rates in people who started with HT within the past 10 years."</u> Many patients counted as "non-regret" are thus LIKELY to express REGRET beyond the study cut-off date. Misreporting results in this manner is another unreliable research error indicative of deception or negligence.

2018 - The Endocrine Society guidelines were published prior to the implosion of the Gender Transition Industry. These guidelines are already outdated and based on assumptions since demonstrated to be false (See, e.g. the recent Cochrane, British N.I.C.E. review, Swedish review, Finnish review, Turban's debunked studies, and the Branstrom Debacle debunked research). None of the recent exposes of massive errors and/or misconduct in transgender medicine research field was known at the time of the Endocrine Society guidelines of 2009 and 2018.

See, THE ENDOCRINE SOCIETY (ES) position(s) on the claims of the Gender Transition Industry is *a political consensus-seeking process* (voting)— not an evidence-seeking scientific research process — and should be reviewed with care. The Endocrine Society clearly states that its practice guidelines "cannot guarantee any specific outcome, nor do they establish a standard of care".

The 2009 ES guidelines noted the low quality (unreliable, invalid) of evidence in this field. E.g. "Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence, which was low or very low."

See, Wylie C. Hembree, Peggy Cohen-Kettenis, Henriette A. Delemarre-van de Waal, Louis J. Gooren, Walter J. Meyer III, Norman P. Spack, Vin Tangpricha, and Victor M. Montori*Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline, J Clin Endocrinol Metab. September 2009, 94(9):3132–3154. doi: 10.1210/jc.2009-0345.

First Corrected version: See, Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2018 Feb 1;103(2):699]

Second corrected version: 2018 published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759]. J Clin Endocrinol Metab. 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658

2019 TAVISTOCK DEBACLE — Professor Michael Biggs of Oxford - THE AFFIRMATION DRUGS ARE EXPERIMENTAL TREATMENTS - AFTER TREATMENT PATIENTS REPORTED <u>GREATER</u> SELF-HARM, <u>MORE</u> BEHAVIORAL and EMOTIONAL PROBLEMS and <u>GREATER</u> DISSATISFACTION WITH THEIR BODY...

Regarding the UK's Tavistock and Portman NHS Trust's Gender Identity Development Service's <u>experimental trial</u> of puberty blockers for early teenagers with gender dysphoria. Oxford's Professor Michael Biggs wrote, "To summarize, GIDS launched a study to <u>administer experimental drugs to children suffering from gender dysphoria.</u>" "After a year on GnRHa [puberty blockers] <u>children reported greater self-harm</u>, and <u>girls experienced more behavioral and emotional problems and expressed greater dissatisfaction with their body—so puberty blockers actually exacerbated gender dysphoria.</u>" (See,

Michael Biggs, "Tavistock's Experimentation with Puberty Blockers: Scrutinizing the Evidence," TransgenderTrend.com, March 5, 2019.)

2019 - IN GREAT BRITAIN, METHODOLOGICAL AND ETHICAL DEFECTS IN GENDER DISCORDANT "TRANSGENDER" RESEARCH and PRACTICES HAVE BEEN PUBLICLY EXPOSED, See, e.g., The British Gids Clinic Controversies:

This reports noted below support my ongoing investigative hypothesis that the Gender Transition Industry is engaged in systemic, negligent, and/or unethical efforts to distribute misleading and/or incomplete information to patients, the scientific community, and the public. The Gender Transition Industry's systemic efforts appear to include multiple methods of deceptive misreporting including A) a failure to properly design research to search for key evidence, B) a misleading failure to properly report key evidence and methodological limitations and/or C) the improper minimizing of key evidence. The documented failures of the Gender Transition Industry with regard to informed consent, failures of scientific methodology, and the use of experimental treatments on unsuspecting patients-families appear to involve violations of standards of care and ethical requirements.]

E.G.: THE BBC REPORT of 2019: See, Cohen, D. and Barnes, H., Transgender treatment: Puberty blockers study under investigation, BBC Newsnight 22 July 2019. https://www.bbc.com/news/health-49036145

"In 2019, England's only NHS youth gender clinic (Gids) lowered the age at which it offered children puberty blockers, partly based on research showing A) an increase in suicide risk following treatment and B) that virtually all young people who took the puberty blocker hormones went on to take cross-sex hormones (while 80% or so of untreated children naturally grow out of their "gender dysphoria" phase by adulthood and accept their biological, natal gender).

"Experts on clinical trials have criticized the design of the study, which they say makes it hard to tell if the reported effects were due to the puberty blockers or something else. But experts said they warranted further investigation."

[NOTE: An alternative hypotheses under investigation: Are the unusual methodological errors reported for Gender Transition Industry practices, research, and treatments the result of gross negligence, politically tainted pseudoscience, or something else?]

"Before 2011, the Gender Clinic (Gids) would give puberty blockers to children only once they had turned 16.... And in 2011, a medical study was approved through which younger children could access these drugs. "Acknowledging the weak evidence for the use of these drugs (hormones), the research team, made up of Gids and University College Hospitals staff, set out to "evaluate the psychological, social and physical effects" of the blockers on a carefully selected group of young people.

Details about risks - such as potential adverse effects on bone strength, the development of sexual organs, body shape or final adult height - were provided in a patient information sheet. But **BBC** Newsnight found certain information had not been included. Previous research had suggested all young people who took the blockers went on to take cross-sex hormones - the next stage towards fully transitioning to the opposite gender. "But patients and parents were not told this in the information sheet." [Note: This report appears to document a serious informed consent violation.]

[NOTE: Are the unusual methodological-ethical errors reported for Gender Transition Industry practices and treatments the result of gross negligence, politically tainted pseudoscience, or something else?

"I don't see that the parents and their children could really have given informed consent given the lack of information that was provided," said Michael Biggs, associate professor of sociology at Oxford University. Prof Biggs... added: "They were not given the information they needed in order to take this momentous life-changing step." He gave BBC Newsnight a series of documents relating to the research study he had obtained via freedom of information requests, which were independently looked at.

[NOTE: Such reported failures of informed consent, defects in methodology, and *the use of experimental treatments on unsuspecting patients-families* appear to be serious violations of ethical, practice, and/or licensing rules.]

Preliminary data for 30 of the 44 young people on the study was made available to the Tavistock's board in 2015. **It showed** that *after* a year on puberty blockers, *there was a significant increase found in those answering the statement "I deliberately try to hurt or kill myself"*. See, Tavistock and Portman Foundation NHS Trust. Preliminary results from the early intervention research. In Tavistock and Portman Foundation NHS Trust, Board of Directors Part One: Agenda and Papers: Appendix 7; 50–55. Tavistock and Portman Foundation NHS Trust, June 2015 (https:// tavistockandportman.nhs.uk/about-us/governance/board-of-directors/ meetings/).

"Prof Susan Bewley (Emeritus Honorary Professor, King's College London Department of Obstetrics & Women's Health), who chairs Healthwatch, a charity for science and integrity in healthcare, is one of a number of doctors raising concerns about the lack of evidence in this area of medicine. She said seeing any change around suicidal thoughts "is very worrying". "Good medical practice would normally be very reflective about an increase in harms," she added."

"Because of *flaws [methodological defects] in how the study was set up*, it is not possible to infer cause and effect or even to say whether rates of suicidal thoughts are higher or lower in this group than in children with gender dysphoria who don't take puberty blockers. *The study had no control group*, of children not taking the drugs, to compare with the observed results. In addition, the outcomes it was measuring were unclear. Nevertheless, experts say these observations should have given Gids pause for thought.

Gids told Newsnight: "All patients were seen regularly by mental health professionals. They concluded that there was no evidence of harms that could be directly attributed to the treatment and that continuation of the study was appropriate."

[NOTE: This appears to be additional, publically exposed, documented evidence of Gender Transition Industry advocates providing incomplete, misinformation to the public and patients. Research has shown that mental health professionals have no relevant reliable-nor valid magical methods for deciphering the truth or falsity of patient reports of gender dysphoria and no reliable nor valid ways of predicting suicide in specific patients. They have no "lie detection" methodology better than flipping coins and they apply "clinical judgment" methods that are often no better than lay persons."(See a detailed discussion of the relevant science in this declaration.) For Gids to ward off responsibility for experimenting on children by assuring the public that "mental health professionals" were involved appears to be another example of not providing complete, accurate, proper information.]

The early data [showing an increase in suicidal ideation] was not shared with the Health Research Authority, despite its demands for updates on the study over a period of three years. In response to BBC Newsnight sharing this preliminary data and other concerns about the study, Teresa Allen, chief executive of the HRA, said: "The information that Newsnight has brought to our attention has not been raised with us before. "We will therefore investigate further, which may include a review of the original ethics opinion."

[NOTE: This is apparently yet another public record of the Gender Transition Industry's deceptive misinformation and apparent unethical misconduct. Note that Dr Brown's expert declaration for the plaintiffs in this (Kadel v Folwell) case appears to be another example of this very same type of brazen misinformation — Dr Brown appears to claim there is no controversy in this field!]

BBC Newsnight's investigation comes amid growing concerns over the way Gids is operating. In an open letter, former Gids (Gender Clinic) clinician Dr Kirsty Entwistle raised concerns over the way puberty blockers were being presented to children as "fully reversible", when their long-term impact was unknown. She also said staff were unable to raise concerns without risking being branded transphobic. [politicized "cancel culture"] See, open letter at [https://medium.com/@kirstyentwistle/an-open-letter-to-dr-polly-carmichael-from-a-former-gids-clinician-53c541276b8d].

Tavistock and Portman Trust chief executive Paul Jenkins told BBC Radio 4's Today programme: "Puberty blockers are reversible."

[NOTE: This is apparently yet another public record - documented on BBC video — of Gender Transition Industry *deceptive misinformation and unethical misconduct* — a clear failure to provide

accurate information on risks and benefits of the treatment — providing such misinformation to a patient would be a serious violation of proper informed consent requirements.]

He said Gids was looking at processes to make it easier for clinicians to focus on their work, "rather than being swayed or influenced by the very heated debate"... (Note: This is the heated international medical, scientific, and ethical debate that Plaintiffs' expert Dr Brown apparently was not aware of or wishes to ignore.) See, Cohen, D. and Barnes, H., Transgender treatment: Puberty blockers study under investigation, BBC Newsnight 22 July 2019. https://www.bbc.com/news/health-49036145

2020 and 2021 - THE GENDER TRANSITION INDUSTRY IMPLODES — RESEARCH DEFECTS and UNETHICAL MISCONDUCT ARE WIDELY EXPOSED:

2020 - THE COCHRANE REVIEW - GENDER AFFIRMATION REMAINS EXPERIMENTAL: "INSUFFICIENT EVIDENCE" FOR "AFFIRMATION" INTERVENTIONS = STILL AN EXPERIMENTAL TREATMENT: The widely respected Cochrane review examined hormonal treatment outcomes for male-to-female transitioners over 16 years. They found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition."

It is remarkable that <u>decades after the first transitioned male-to-female patient, quality evidence</u> <u>for the benefit of transition is still lacking</u>. See, Haupt, C., Henke, M. et. al., <u>Cochrane Database of Systematic Reviews</u> Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020.

2020 - GRIFFIN REVIEW In the Bulletin of the Royal College of Psychiatrists - PSYCHIATRIC DISORDERS PERSIST (after "transitioning") so use a SUPPORTIVE, EXPLORATORY APPROACH (not Mandated Affirmation) — In the Bulletin of the Royal College of Psychiatrists See, Griffin, L., Clyde, K., Byng, R., Bewley, S., Sex, gender and gender identity: a re-evaluation of the evidence. BJPsych Bulletin (2020) doi:10.1192/bjb.2020.73, Cambridge University Press, 21 July 2020, the authors noted the hazardous error of mandating "affirmation treatments" — thus requiring the negligent practice of Confirmation Bias — rather than properly and carefully exploring alternative hypotheses — the standard, required ethical, medical standard of practice. ... As Griffin discussed, "Attempts to properly explore, formulate and treat coexisting mental illness in gender dysphoric populations, including that relating to childhood trauma, might be considered tantamount to 'conversion therapy'. Although mental illness is overrepresented in the trans population it is important to note that gender non-conformity itself is not a mental illness or disorder. As there is evidence that many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive, exploratory approach with gender-questioning patients should not be considered conversion therapy."... In addition, Griffin et al wrote: "Transgender support groups have emphasized the risk of suicide. After controlling for coexisting mental health problems, studies show an increased risk of suicidal behaviour and self-harm in the transgender population, although underlying causality has not been convincingly demonstrated. (See, Marshall E, Claes L, Bouman WP, Witcomb GL, Arcelus J. Non-suicidal self-injury and suicidality in trans people: a systematic review of the literature. Int Rev Psychiatry 2016; 28: 58-69.) Activists and too many providers have used a fear of suicide to push experimental unproven treatments.

2020 – LONDON HIGH COURT: THE ETHICAL RISKS OF THE STILL EXPERIMENTAL GENDER AFFIRMATION INTERVENTIONS HAVE BEEN HIGHLIGHTED BY AN INTERNATIONALLY REPORTED LAWSUIT IN BRITAIN: See, Puberty blockers: Under-16s 'unlikely to be able to give informed consent', BBC, 1 December 2020 "Children under 16 with gender

dysphoria are unlikely to be able to give informed consent to undergo treatment with puberty-blocking drugs, three High Court judges have ruled.... "Given the long-term consequences of the clinical interventions at issue in this case, and given that the treatment is as yet innovative and experimental, we recognise that clinicians may well regard these as cases where the authorization of the court should be sought prior to commencing the clinical treatment."... The judges have effectively split the issue into stages. They concluded a child under 13 is "highly unlikely" to be able to give informed consent and at 14 and 15 it is still "doubtful" they can fully understand the implications of the medication....Even for 16 and 17-year olds the ruling says it may be appropriate to involve the courts in the decision.... The judges point to the lack of evidence about the long-term effects of puberty blockers as adding to the difficulty of consent, but in effect, the courts will now play a much greater role in decisions, which are already highly emotionally charged... Paul Conrathe, the solicitor for both claimants, said the ruling was "an historic judgment that protects children who suffer from gender dysphoria". He said the judgment showed "that a culture of unreality has become embedded in the Tavistock". "This may have led to hundreds of children receiving this experimental treatment without their properly informed consent," he said. See, https://www.bbc.com/news/uk-england-cambridgeshire-55144148

2020 - D'ANGELO REVIEW OR TURBAN'S DEFECTIVE RESEARCH ... AN ONLINE "CONVENIENCE SAMPLE": D'Angelo, R., Syrulnik, E., Ayad, S. et al. One Size Does Not Fit All: Support Psychotherapy for Gender Dysphoria. Arch https://doi.org/10.1007/s10508-020-01844-2 "Turban used the 2015 USTS survey ... a convenience sampling, a methodology which generates low-quality, unreliable data (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender political advocacy organizations and subjects were asked to "pledge" to promote the survey among friends and family. This recruiting method yielded a large but highly skewed politicized sample."...." neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design."... "We call on the scientific community to resist the stigmatization of psychotherapy for GD and to support rigorous outcome research investigating the effectiveness of various psychological treatments aimed at ameliorating or resolving GD."

2020 - THE TURBAN ONLINE SURVEY RESEARCH DEBACLE ... PUBLIC EXPOSURE OF TURBAN'S SERIOUS RESEARCH DEFECTS - Another example of the Gender Transition Industry's misleading and deceptive misreporting of incompetent research. ... See 2020 scathing D'ANGELO REVIEW.... " neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design."... Turban used the 2015 USTS survey ... a convenience sampling, a methodology which generates low-quality, unreliable data (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender political advocacy organizations and subjects were asked to "pledge" to promote the survey among friends and family. This recruiting method yielded a large but highly skewed politicized sample."... Turban's defective project "does not differentiate between diagnostic evaluations or a specific therapeutic intervention. There is also no information about whether the focus of the encounter was gender dysphoria or another condition." ... Turban's analysis is compromised by serious methodological flaws, including "reliance on survey questions with poor validity'... "Turban et al.'s (2020) finding of an association between the recall of GICE and scoring ≥ 13 actually suggests that the USTS participants recalling GICE were more likely to have a severe mental illnesses diagnosis than those not recalling GICE."... "Turban's failure to control for the subjects' baseline mental health makes it impossible to determine whether the mental health or the suicidality of subjects worsened, stayed the same, or potentially even improved after the nonaffirming encounter."... "Another measure of psychological distress chosen by Turban et al.—substance misuse—was not significantly different between GICE and the non-GICE group. More importantly, there is a lack of consistency in the suicide measures. While lifetime suicide attempts were elevated among the GICE group, total suicide attempts in the prior 12 months, as well as suicide attempts requiring hospitalization, which generally indicate more serious attempts rather than non-suicidal self-injury, were

not significantly different between the two groups."... "Turban et al.'s choice to IMPROPERLY interpret the said association as evidence of harms of GICE disregards the fact that neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design."... "Arguably, even more problematic than the flawed analysis itself is the simplistic "affirmation" versus "conversion" binary, which permeates Turban et al.'s (2020) narrative and establishes the foundation for their analysis and conclusions."... "at worst, it effectively mis-categorizes ethical psychotherapies (e.g., CBT) that do not fit the "affirmation" descriptor as conversion therapies. Stigmatizing non-"affirmative" psychotherapy for GD as "conversion" will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress."...

2020 - THE TURBAN PEDIATRICS RESEARCH ONLINE SURVEY DEBACLE: See, Turban JL, King D, Carswell JM, et al. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, Pediatrics Feb 2020, 145 (2) e20191725; DOI: 10.1542/peds.2019-1725.

Multiple Letters to the Editor criticized Dr. Turban's 2020 study in Pediatrics for multiple methodological errors. https://pediatrics.aappublications.org/content/145/2/e20191725/tab-e-letters#re-pubertal-suppression-for-transgender-youth-and-risk-of-suicidal-ideation

Scott S. Field, Den A. Trumbull, RE: Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation.

Patrick H Clarke, RE: Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. TURBAN used an Unreliable, biased sampling methodology: "Using a cross-sectional online survey of 20,619 transgender adults aged 18 to 36 years..." [2015 U.S Transgender Survey. Online survey of transgender and "genderqueer" adults recruited from trans-friendly websites. NO ID, NO evidence of identities, NO way to measure bogus subjects, NO medical diagnosis for entry.]... No causation can be determined from this retrospective, cross-sectional design ... ("...cross-sectional design, does not allow for determination of causation.").... TURBAN failed to even assess Desisters and Regretters ... Turban claimed that desisters and regretters would "not be likely" in this study group, which also only included adults, so his study "does not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender." ... "Turban's misleading (deceptive?) claim of lower suicidal ideation for treated patients excluded the most seriously mentally ill patients that would have been DENIED affirmation treatment — "those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression but did not receive it, had lower odds of lifetime suicidal ideation (adjusted odds ratio = 0.3; 95% confidence interval = 0.2-0.6)."... Turban appears to have "forgotten" to report that See, Table 3. Under "Suicidality (past 12 months)" reductions for suppressed group v non were seen for ideation (50.6% v 64.8%) and "ideation with plan" (55.6% v 58.2%). But suicidal ideation with plan and suicide attempt" for the suppressed group INCREASED after treatment to 24.4% v 21.5% for the non-treatment group."... The most clinically significant result in this study — that "Affirmation Treatments INCREASED SERIOUS SUICIDE ATTEMPTS — was IGNORED BY THE AUTHORS (i.e., not statistically significant but clinically significant) = "Suicide attempts resulting in inpatient care" = 45.5% for suppression groups v. 22.8% for non. [This is clearly a very "UNsuccessful treatment" if 45% attempted suicide!]. In sum, Turban et al. ignored their own finding that a history of puberty suppression was associated with an INCREASE in recent serious suicide attempts."... In sum, the Turban 2020 Pediatrics study, based on an unverified US Transgender Online Survey, tells us little about the effects of puberty suppression on children with gender dysphoria. See, Michael Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. Archives of Sexual Behavior, accepted 14 May 2020, DOI: 10.1007/s10508-020-01743-6

2020 - LONDON COURT RULING ... "given that the treatment is as yet innovative and <u>experimental"</u>... CHILDREN HIGHLY UNLIKELY TO BE ABLE TO CONSENT TO "AFFIRMATION" INTERVENTIONS:

See, Dyer, C., Children are "highly unlikely" to be able to consent to taking puberty blockers, rules High Court BMJ 2020; 371 doi: https://doi.org/10.1136/bmj.m4699 (Published 01 December 2020) Cite this as: BMJ 2020;371:m4699

Children under 16 cannot consent to the use of puberty blockers for gender dysphoria unless they can understand the immediate and long-term consequences of the treatment, which is unlikely, the High Court in London has ruled.

See, also Ruling on the application of Quincy Bell and A v Tavistock and Portman NHS Foundation Trust and others. [2020] EWHC3274 (Admin). https://www.judiciary.uk/judgments/r-on-the-application-of-quincy-bell-and-a-v-tavistock-and-portman-nhs-trust-and-others/.

The legal challenge was brought against the Tavistock and Portman NHS Trust, which runs the UK's only gender reassignment service for young people. Keira Bell, 23, who was treated as a teenager, and "Mrs A," the mother of a 15 year old with autism who was on the waiting list for treatment, challenged the service's policy and practice on the use of puberty blockers. They argued that children were unable to give informed consent for the treatment.

Victoria Sharp, president of the Queen's Bench Division, sitting with Lord Justice Lewis and Mrs Justice Lieven, said it was "highly unlikely" that a child aged 13 or under would be competent to give consent to the administration of puberty blockers. She said that the judges were "very doubtful" that a child aged 14 or 15 could understand and weigh the long term risks and consequences of the administration of puberty blockers.

For children of 16 and over there is a presumption that they have the ability to consent to medical treatment. But, "given the long term consequences of the clinical interventions at issue in this case, and *given that the treatment is as yet innovative and experimental*, we recognise that clinicians may well regard these as cases where the authorisation of the court should be sought prior to commencing the clinical treatment," said Sharp.

Bell took puberty blockers at age 15 or 16 and later was given male hormones and had her breasts removed. She has since "re-transitioned" back to living in accord with her female sex. Sharp said that puberty blockers had been prescribed to children as young as 10 years.

The trust, and other trusts to which it referred patients for treatment, had argued that taking hormone blockers and later cross sex hormones were entirely separate stages of treatment. Sharp concluded, "It is said therefore the child needs only to understand the implications of taking puberty blockers alone . . . in our view this does not reflect the reality. The evidence shows that the vast majority of children who take puberty blockers move on to take cross sex hormones, that stages 1 and 2 are two stages of one clinical pathway and, once on that pathway, it is extremely rare for a child to get off it."

2020 -Schumm and Crawford Review SHOWING SEVERE DEFECTS IN AFFIRMATION RESEARCH BY Olson et al. 2016b; Durwood, McLaughlin, and Olson 2017 Schumm and Crawford asked the question: "Is good science being thrown under the bus for the sake of politically correct agendas?"

As Schumm and Crawford further noted: "The results should have been interpreted as evidence that even with high levels of parental support, transgender children have lower levels of mental health, especially with respect to higher levels of anxiety and lower levels of self-worth...

Negligence, Fraud, or Political Ideology?: In the case of Olson et al. (2016b) and Durwood, McLaughlin, and Olson (2017), not only were there numerous statistical errors (Schumm et al. 2019), but a great deal of data and results, including some significant results, were not reported until the authors were queried. Not reporting significant results may occur but when the apparent conclusion is that there were not any significant results, leaving out significant findings can be seen as self-serving to the idea of maintaining support for the null hypothesis regardless of the facts. Is good science being thrown under the bus for the sake of politically correct agendas? It's difficult to escape a sense that such is not an uncommon occurrence in areas of considerable political controversy. One has to wonder what other areas of controversial science may have been infected with this type of problem." (See, Schumm, WR and Crawford, DW, Is Research on Transgender Children What It Seems? Comments on Recent Research on

Transgender Children with High Levels of Parental Support, The Linacre Quarterly, 2020, Vol. 87(1) 9-24. DOI: 10.1177/0024363919884799

2020 - GREAT BRITAIN REVIEW OF GENDER AFFIRMATION INTERVENTIONS SHOWS "VERY LOW" QUALITY EVIDENCE: GB NICE REVIEW OF Oct 2020 - See, Deborah Cohen and Hannah Barnes for BBC Newsnight - "Evidence for puberty blockers use <u>very low</u>, says NICE"

The evidence for using puberty blocking drugs to treat young people struggling with their gender identity is "very low", an official review has found. The National Institute of Health and Care Excellence (NICE) said existing studies of the drugs were small and "subject to bias and confounding".

The assessment of the evidence into the drugs was commissioned by NHS England. It is part of a review into gender identity services for children and young people. See, https://arms.nice.org.uk/resources/hub/1070905/attachment

NICE found it was <u>difficult to draw conclusions from existing studies because of the way they</u> <u>had been designed.</u> They were "all small" and <u>didn't have control group</u>s, which are used to directly compare the effect of different treatments.

There were <u>other issues with the studies too</u>, <u>such as not describing what other physical and mental health problems a young person may have alongside gender dysphoria</u>.

The review said there was <u>"very little data" on any additional interventions</u> - such as counselling or other drug treatments - the young people may have had alongside taking puberty blockers, and this could bias the results.

The impact of puberty blockers on bone density has been raised as a potential concern by some experts previously. However, NICE found that without a "comparator group", it was not known whether any observed changes in bone density "are associated with GnRH analogues or due to changes over time".

Some argue that carrying out a controlled trial - which would provide better quality evidence - might be difficult because of the potential impact on mental health if treatment is withheld in one group. NICE accepted this, but said offering psychological support to compare puberty blockers "may reduce ethical concerns in future trials". The review found no evidence of cost-effectiveness of treatment.

NICE also reviewed the evidence base for gender-affirming hormones - sometimes known as cross-sex hormones. See, https://arms.nice.org.uk/resources/hub/1070871/attachment

The review found the evidence of clinical effectiveness and safety of gender-affirming hormones was also of "very low" quality. "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria," NICE said. Both documents were prepared by NICE in October 2020 and will now help inform Dr Hilary Cass's independent review into NHS gender identity services for children and young people. See, https://www.bbc.com/news/health-56601386

2020 - THE MALONE, HRUZ, MASON and BECK et al. LETTER TO THE EDITOR DOCUMENTING RESEARCH DEFECTS IN THE GENDER TRANSITION INDUSTRY:

See, Malone WJ, Hruz PW, Mason JW, Beck S. Letter to the Editor from William J. Malone: "Proper Care of Transgender and Gender-Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective". The Journal of Clinical Endocrinology & Metabolism. **2020.**

Walch et al. endorse the ES Position that puberty suppression (PS), cross-sex hormones (CSH) and surgeries are "effective," "relatively safe," and have been "established as the standard of care" [2]. However, a growing body of evidence shows adverse effects on bone growth, cardiovascular health, and fertility, as well as transition regret.

Walch et al. also endorse the ES Position claiming there is an established "durable biological underpinning" to gender identity (GI) *2]. However, the first citation supplied by the ES for this position <u>highlights contradictory studies</u> and describes the biological origin of GD as simply <u>a "current hypothesis"</u> *7+. The other citation describes GI as a "complex interplay of biological, environmental, and cultural factors" *8+. Further, <u>the concept of "durability" is challenged by the fact that most cases of GD in children naturally resolve by adulthood</u>. It is <u>precisely this lack of durability that should give pause to</u>

<u>administering potentially harmful and often irreversible medical interventions to young patients with GD.</u>

The ES Position Statement also overlooks a key fact that the existing body of evidence regarding treatment outcomes for GD was not only graded as "low quality", but has been derived from a vastly different population than the one presenting with GD today. Currently, GD predominantly presents in adolescent females with no childhood history, in contrast to the prior population which was predominantly male with early onset of gender dysphoria.

Walch A, Davidge-Pitts C, Safer JD, Lopez X, Tangpricha V, Iwamoto SJ. Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective. J Clin Endocrinol Metab. Jan 23 2021;106(2):305-308. doi:10.1210/clinem/dgaa816

Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. Nov 1 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658

Rosenthal SM, Hembree WC, Cohen-Kettenis PT, et al. Response to Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". J Clin Endocrinol Metab. Nov 1 2019;104(11):5102-5103. doi:10.1210/jc.2019-00930

2020 - THE Branstrom DEBACLE - ... EXPOSURE OF Branstrom et al's MULTIPLE, SERIOUS RESEARCH DEFECTS: Another example of the Gender Transition Industry's misleading and deceptive misreporting of incompetent research.

In 2020, Branstrom, et al, published a research report claiming that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." This research appeared to be an historic first — empirical evidence that gender transition surgeries demonstrated long-term benefits. (See, Branstrom, Pachankis: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177: 727–734.)

Almost immediately, however, the relevant scientific community — including multiple MD, PhD methodology experts — exposed the Branstrom study *as a series of methodological blunders and/or manipulative deceptions*. Multiple science experts concluded that, "These methodological shortcomings preclude any statement on the suitability of early surgery in persons seeking treatment for gender noncongruence based on the results presented in this article." They also noted evidence supporting the theory that these "errors" could well be purposeful and designed to support an ideological perspective when they noted, "people diagnosed with gender incongruence have a dramatically worse overall mental health outcome (after "transitioning" treatments) than the general population, which is, in fact, the answer to their stated aim and research question, but this (most essential) finding is not even referred to in the title or in the Conclusions section of the article." (See, Kalin, N.H., Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process by the Editor-in-Chief The American Journal of Psychiatry, Am J Psychiatry 2020; 177:764; doi: 10.1176/appi.ajp.2020.20060803; See also, Anckarsäter, H., (MD, Ph.D.) and Gillberg, C., (M.D., Ph.D.) Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, Am J Psychiatry 2020; 177:764–765; doi: 10.1176/appi.ajp.2020.19111117.

Additional methodology experts noted other serious flaws in the Branstrom study including: "For those whose last surgery was 10 or more years earlier, how many completed suicide, died of other causes, or left Sweden prior to study initiation?" The authors failed to find out (or hid negative results). The methodology experts also noted, "A drop in hospitalizations for suicide attempts alone provides a very incomplete picture. When the data for such findings are accessible in the Swedish national registers, this omission is glaring. The lack of control subjects, the limited 1-year time frame, and the avoidance of examining completed suicides and psychiatric hospitalizations are substantial study shortfalls."..."The study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, this study lacks the evidence to support its pro gender-

affirmation surgery conclusion." See, Van Mol, A., Laidlaw, M. K., Grossman, M., McHugh, P., Gender-Affirmation Surgery Conclusion Lacks Evidence, Am J Psychiatry 177:8, August 2020 ajp.psychiatryonline.org 765.

Additional methodology experts noted that "The study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the Branstrom study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially HIGH in the year AFTER the completion of gender-affirming surgery [It is telling that the authors somehow ignored this most essential finding -Note this appears to be more potential evidence of deception, research fraud, and/or licensing violations.] ..." See, Curtis, D. (M.D., Ph.D.), Study of Transgender Patients: Conclusions Are Not Supported by Findings, Am J Psychiatry 2020; 177:766; doi: 10.1176/appi.ajp.2020.19111131.

Still more reviewers concluded, "The data presented in Figure 1 in the article support findings from previous studies showing that *transgender individuals have baseline mental health distress that is higher than that of the general population, but it is not possible to conclude from these data whether genderaffirming surgery relieves that distress.*"... "Because of the *limitations in the study design*, it is not possible to determine the cause of the differences in mental health service utilization or whether true reductions in psychological distress actually occurred. (They failed to even measure increased suicides, etc.) ... "Therefore, the authors 'conclusion that the results of their study should be interpreted to support policies that provide gender-affirming surgeries *cannot be supported*." See, Malone, W. and Roman, S., Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, Am J Psychiatry 2020; 177:766–767; doi: 10.1176/appi.ajp.2020.19111149.

Finally, yet another (MD, PhD) reviewer noted in detail... "The Branstrom and Pachankis study on mental health treatment and suicide attempts ... is misleading because the study design is flawed." "The authors first found what was already known ... the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population (both before AND after "transitioning"). The authors then explored if the risk for mental health treatment changes as a function of years since starting HORMONAL treatment. They find NO effect (odds ratio = 1.0), but they do find a trend toward INCREASED risk of suicide attempts as a function of years since starting HORMONAL treatment. They somehow failed to publish this essential finding. [Note ... more potential evidence of deception, research fraud, or licensing violations.] In their key analysis, allegedly showing that gender-affirming surgery decreases risk for psychiatric treatment and suicide attempts, they relate these negative outcomes to the number of years since surgery. Contrary to what the authors repeatedly claim, they do not employ a longitudinal design but conduct a retrospective analysis unfit for their research question. First, the authors include only persons who were alive in 2014. That means that those who died by SUICIDE before 2014—and hence were at highest risk for suicide attempt—are EXCLUDED from the data and confound the results. [Note ...this appears to be still more potential evidence of deception, research fraud, and/or licensing violations.] Second, any analysis starting with a negative event is bound to find a decreased risk for related negative outcomes with increasing time after the event. To exemplify this point, the rate of antidepressant treatment would decrease with time after a suicide attempt. This does not mean that suicide attempts cause a decrease in risk of antidepressant treatment; it is merely a case of regression toward the mean. Third, persons undergoing gender transition have, by definition, contact with mental health services in Sweden. After the transition, persons are followed up by endocrinologists and sometimes general practitioners; only those with persistent mental health issues are followed in psychiatric care. The authors ' finding of lower rates of mental health treatment with increasing time after surgery is therefore not only a case of regression toward the mean, but it also follows from the standards of care and is not a proxy for improved mental health. Because the authors do not present data prior to gender affirming surgery, the study is uninformative with regard to the effects on psychiatric morbidity. Moreover, the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with HIGH risk for SUICIDE attempt. [Note ... still more potential evidence of deception, research fraud, or licensing violations.] Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes." See, Landén, M. (M.D., Ph.D.) The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, Am J Psychiatry 2020; 177:767–768; doi: 10.1176/appi.ajp.2020.19111165.

Yet another MD, PhD expert severely criticized the Branstrom, et. al. study noting: The results confirm what is already known, that is, that as a group, persons with gender dysphoria suffer from poorer psychiatric health than the general population. However, the title of the article implies that gender corrective surgery promotes mental health in this group, and the authors conclude in the Abstract section that the study "lends support to the decision to provide gender affirming surgeries to transgender individuals who seek them." In my opinion, this conclusion is not supported by the data presented in the article. [Note ... more potential evidence of deception, research fraud, or licensing violations.] The most straightforward method to test whether surgery contributes to better psychological health would be to compare the health of those who underwent surgery with those who did not. Of the persons diagnosed with gender dysphoria presented in the article, 1,018 had undergone surgery, while 1,661 had not. There were 22 individuals who were hospitalized in 2015 for a suicide attempt. The authors do not state how many of these individuals had received surgery, but this may be calculated by combining the data from Table 3 and Figure 1 in the article. Figure 1 shows the proportion of persons with gender dysphoria who were hospitalized for suicide attempt in 2015, grouped according to the time that had elapsed since the last gender-corrective surgery. Table 3 shows the number of individuals with gender dysphoria, grouped according to the time elapsed since last surgical operation ("Time since last gender-affirming surgical treatment"). By combining these data, we can calculate that 10 of the suicide attempts (2.8% of 353) occurred during the same year that the last surgical correction was made ("perioperative" group in Figure 1). Two cases occurred 1 year after the last surgical correction (0.9% of 221) and one case 2–3 years after the last surgical treatment (0.5% of 198), while none occurred more than 3 years after the last surgery. Thus, 13 individuals (10 plus two plus one) of the 22 persons who were hospitalized for a suicide attempt in 2015 had undergone gender corrective surgery. Consequently, nine of them (22 minus 13) had not undergone any gender-affirmation surgery. This corresponds to an odds ratio of 2.37 (95% CI= 1.01-5.56, p=0.047). Hence, among the individuals examined in the study, the risk of being hospitalized for a SUICIDE ATTEMPT was 2.4 times HIGHER if they had undergone gender-corrective surgery than if they had not. [Note this key finding was apparently hidden or not noticed by the authors ... more potential evidence of deception, research fraud, or licensing violations by the research authors.] Whether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do not support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria." See, Wold, A. (M.D., Ph.D.) Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, Am J Psychiatry 2020; 177:768; 10.1176/appi.ajp.2020.19111170.

In addition, yet another pair of reviewers severely criticized the Branstrom study noting: "The qualitative approximation of this curve with the reduction described by Branstrom and Pachankis (in their Figure 1) is striking. Therefore, accounting for the increase in mental health issues from 2005, together with an assumption of INCREASED mental health treatment due to this surgery, fits the data in the article and **OVERTURNS** the authors stated conclusions, [Note ... more potential evidence of deception, research fraud, or licensing violations by the research authors.] suggesting that sex reassignment surgery is in fact associated with INCREASED mental health treatment. See, Ring, A. (PhD) and Malone, W., Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, Am J Psychiatry 2020; 177:768–769; doi: 10.1176/appi.ajp.2020.19111169.

It should be noted, that after this very public exposure of the Branstrom Debacle by multiple expert reviews, the research authors admitted their conclusions were in error (confessed) and that "more research" is needed to answer the question of whether Gender Transition Industry treatments are helpful or harmful, long-term. The authors admitted, "Studies employing prospective cohort designs are needed to better understand suicidality within this group and its associations with gender-affirming

care... (and)... When comparing the mental health treatment outcomes between the two groups (Table 1), we found no significant difference in the prevalence of treatment for mood disorders and no significant difference in the prevalence of hospitalization-suicide attempts. "and stunningly they admitted they had failed to note that "individuals diagnosed with gender incongruence who had received genderaffirming surgery were MORE likely to be treated for ANXIETY disorder compared with individuals diagnosed with gender incongruence who had NOT received gender-affirming surgery. 'and "While the design clearly establishes that individuals diagnosed with gender incongruence utilized more mental health care than the general population in 2015, especially during the perioperative period, like most extant research on the topic, the design is incapable of establishing a causal effect of gender affirming care on mental health treatment utilization. This retreat and mea culpa was published as Branstrom, R. and Pachankis, J., Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals 'Mental Health: Response to Letters, Am J Psychiatry 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.

[Underlines, italics, and emphases above are added]

In sum, like the Branstrom Debacle ... too many ideologically tainted and methodologically defective research studies suffer from these kinds of *serious errors, improper analyses and harmfully deceptive reports*. Such poorly designed and improperly conducted research studies continue to prevent gender transition "affirmation" treatments from being generally accepted by the relevant scientific community. Finally, the Error Rates for such unproven, experimental "treatments" as well as for the foundational politically-based transgender ideology, are unknown, un-peer-reviewed, and unpublished. [Note: Compare the multiple, scathing reviews by international scientist experts above to Dr Brown's and Dr Schechter's misleading and incomplete expert declarations for the plaintiffs in this case.]

2021 - The Singh, Bradley, and Zucker study — the largest sample to date - found support for the "watchful waiting" no affirmation treatment approach combined when needed with psychotherapy and coping-resilience training.

This research supports the view that an aggressive, intrusive "affirmation" of the Gender Transition Industry's "transitioning treatments" is an unethical, experimental practice which brings an unnecessarily high risk of causing serious, lasting harm to most such children.

In a follow-up study reviewing data on the largest sample to date of boys clinic-referred for gender dysphoria (n = 139) with regard to gender identity and sexual orientation. At follow-up, gender identity/dysphoria was assessed via multiple methods with participants classified as persisters or desisters). Of the 139 participants, 17 (12.2%) were classified as persisters and the remaining 122 (87.8%) were classified as desisters, that is, patients who grew out of their gender dysphoric symptoms and came to accept their natal gender without further symptoms.

Clearly, given that the vast majority of these patients were on a natural developmental path to healthy adjustment without treatment, it would be unethical to engage in an intrusive "affirmation" treatment program using hormones and/or surgery that would be LIKELY to disrupt normal developmental processes producing iatrogenic (treatment caused injuries) harm to many patients. See, Devita Singh1, Susan J. Bradley 2 and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021, Volume 12, Article 632784, www.frontiersin.org.

In addition, these authors discussed the previous 9 studies with sample sizes (excluding those lost to follow-up) ranging from 6 to 79 subjects (Mean age, 26 years). Most of these studies also provided the age at time of first evaluation in childhood, which ranged from a mean of 7 years (47) to a mean of 9 years (48), with an age range from 4 to 12 years. At the time of follow-up, using different metrics (e.g., clinical interview, maternal report, dimensional measurement of gender dysphoria, a DSM diagnosis of GID, etc.), these studies provided information on the percentage of boys who continued to have gender dysphoria (herein termed "persisters") and the percentage of boys who did not (herein termed "desisters" of those who grew out of dysphoria). Of the 53 boys culled from the relatively small sample size studies (Bakwin, Davenport, Kosky, Lebovitz, Money and Russo, Zuger), the percentage classified as persisters was 9.4% (age range at follow-up, 13–30 years). In Green (47), the percentage of persisters was

2% (total n = 44; Mean age at follow-up, 19 years; range, 14–24); in Wallien and Cohen-Kettenis (52), the percentage of persisters was 20.3% (total n = 59; Mean age at follow-up, 19.4 years; range, 16–28); and in Steensma et al. (51), the percentage of persisters was 29.1% (total n = 79; Mean age at follow-up, 16.1 years; range, 15–19). Across all studies, the percentage of persisters was 17.4% (total N = 235), with a range from 0 to 29.1%. See, Devita Singh1, Susan J. Bradley 2 and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021 | Volume 12 | Article 632784, www.frontiersin.org,

These studies appear to support a "watchful waiting" treatment approach combined when needed with psychotherapy and/or coping-resilience training. An aggressive, intrusive "affirmation" of transitioning treatment model appears highly unethical and produces an unnecessarily high risk of causing serious, lasting harm to MOST of these patients.

2021-2020 CARMICHAEL STUDY (2020 also) — <u>HORMONE TREATMENTS DO NOT HELP</u> CHILDREN WITH GENDER DYSPHORIA... BUT DO STUNT GROWTH:

See, Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653 and Dyer, C. Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study. *BMJ* 372, n356, doi:10.1136/bmj.n356 (2021). https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1 BBC summary: https://www.bbc.com/news/uk-55282113journal.pone.0243894. pmid:33529227

Results 44 patients had data at 12 months follow-up, 24 at 24 months and 14 at 36 months. All had normal karyotype and endocrinology consistent with birth-registered sex. All achieved suppression of gonadotropins by 6 months. At the end of the study one ceased GnRHa and 43 (98%) elected to start cross-sex hormones...."We identified no changes in psychological function. Changes in BMD were consistent with suppression of growth. Larger and longer-term prospective studies using a range of designs are needed to more fully quantify the benefits and harms of pubertal suppression in GD."

Self-harm $\underline{\text{did NOT improve}}$ and "no changes in psychological function," meaning no improvement. (Also, "YSR [Youth Self Report] data at 36 months (n = 6) were not analyzed."

"We found **no differences between baseline and later outcomes for overall psychological distress** as rated by parents and young people, nor for self-harm."

CONCLUSION: "We found no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm..."

Puberty blockers used to treat children aged 12 to 15 who have severe and persistent gender dysphoria <u>had no significant effect on their psychological function, thoughts of self-harm, or body image</u>, a study has found.

However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16. The findings, from a study of 44 children treated by the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust in London, have emerged as the trust prepares to appeal against a High Court ruling that led NHS England to pause referrals of under 16s for puberty blockers.

Media = See, Dyer, C. *Puberty blockers: children under 16 should not be referred without court order, says NHS* England. BMJ2020;371:m4717.doi:10.1136/bmj.m4717 pmid:33268453<u>FREE Full TextGoogle Scholar</u>

Media = See, Dyer, C., *Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study*, BMJ 2021;372:n356 doi: https://doi.org/10.1136/bmj.n356 (Published 08 February 2021)

82. SUMMARY OPINIONS:

- There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.
- There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are injured or harmed by such procedures.
- There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.
- There are no long-term, peer-reviewed published, reliable and valid, research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological, or other objective assessment of gender identity or gender dysphoria.
- A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.
- A currently unknown percentage and number of patients reporting gender dysphoria are being manipulated by a peer group, social media, YouTube role modeling, and/or parental social contagion and social pressure processes.
- Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable and valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.
- It would be a serious violation of licensing rules, ethical rules, and professional standards of care for a health care professional to provide gender transition or related procedures to any

patient without first properly obtaining informed consent including informing the patient and/or guardian(s) of the lack of valid and reliable on the long-term risks and benefits of "affirmation" treatments.

- A large percentage of children (over 80% in some studies) who questioned their gender identity will, if left alone, develop an acceptance of their natal (biological) sex.
- Medical treatments may differ significantly by sex according to chromosomal assessment but not gender identity. Misinforming physicians of a patient's biological sex can have deleterious effects on treatment for medical conditions.
- NOT GENERALLY ACCEPTED: Affirmation medical treatments hormones and surgery for gender dysphoria and "transitioning" have not been accepted by the relevant scientific communities (biology, genetics, neonatolgy, medicine, psychology, etc).
- NO KNOWN NOR PUBLISHED ERROR RATES: Gender transition "Affirmation" medical assessments and treatments hormones and surgery for gender dysphoria and "transitioning" have no known, peer reviewed and published error rates the treatments and assessment methods lack demonstrated, reliable and valid error rates.
- POLITICS v. SCIENCE: Political activists, political activist physicians, and politically active medical organizations that operate by voting methodologies (e.g, WPATH, the American Medical Association, the American Academy of Pediatrics, the American Endocrine Society) are not the relevant scientific community, they are politically active professional organizations. These organizations operate via consensus-seeking methodology (voting) and political ideologies (e.g., Critical Theory) rather than evidence-based scientific methodologies.

Paul Hruz, MD, PhD Expert Declaration in Kadel v Folwell

101

- ETHICAL RESTRICTIONS ON EXPERTS: Experts in legal cases have an ethical

obligation to honestly, fairly, and accurately discuss the international controversy regarding the

safety, effectiveness, reliability, and credibility of the Gender Transition Industry.

82. LIMITATIONS ON EXPERT REPORTS: My opinions and hypotheses in this

matter are — as all expert reports — subject to the limitations of documentary and related

evidence, the impossibility of absolute predictions, as well as the limitations of social, biological,

and medical science. I have not met with, nor personally interviewed, anyone in this case. As

always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet

reviewed all of the evidence in this case and my opinions are subject to change at any time as new

information becomes available to me. Only the trier of fact can determine the credibility of

witnesses and how scientific research may or may not be related to the specific facts of any

particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties,

and the public understand and apply reliable scientific, technical, and investigative principles,

hypotheses, methods, and information. I have transmitted this confidential expert report directly

to John Knepper (john@knepperllc.com), for distribution as consistent with the laws of the

appropriate jurisdiction for this case.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United

States of America that the foregoing is true and correct.

Data

04/30/2021

Signed: Pal W 13

PAUL W. HRUZ, M.D., Ph.D.

THE END

Exhibit A

Curriculum Vitae

Date: 04/29/2021 09:26 AM Name: Paul W. Hruz, M.D., Ph.D.

Contact Information

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Present Position

Associate Professor of Pediatrics, Endocrinology and Diabetes Associate Professor of Pediatrics, Cell Biology & Physiology

Education

1987	BS, Chemistry, Marquette University, Milwaukee, WI
1993	PhD, Biochemistry, Medical College of Wisconsin, Milwaukee, WI
	Elucidation of Structural, Mechanistic, and Regulatory Elements in 3-Hydroxy-3-Methlyglutaryl-Coenzyme A Lyase, Henry Miziorko
1994	MD, Medicine, Medical College of Wisconsin, Milwaukee, WI
1994 - 1997	Pediatric Residency, University of Washington, Seattle, Washington
1997 - 2000	Pediatric Endocrinology Fellowship, Washington University, Saint Louis, MO
2017	Certification in Healthcare Ethics, National Catholic Bioethics Center, Philadelphia, PA

Academic Positions / Employment

1996 - 1997	Locum Tenens Physician, Group Health of Puget Sound Eastside Hospital, Group Health of
	Puget Sound Eastside Hospital, Seattle, WA
2000 - 2003	Instructor in Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St.
	Louis, MO
2003 - 2011	Assistant Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St.
	Louis, St. Louis, MO
2004 - 2011	Assistant Professor of Pediatrics, Cell Biology & Physiology, Washington University in St.
	Louis, St. Louis, MO
2011 - Pres	Associate Professor of Pediatrics, Cell Biology & Physiology, Washington University in St.
	Louis, St. Louis, MO

2011 - Pres	Associate Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2012 - 2017	Division Chief, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO

Clinical Title and Responsibilities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per yr, St. Louis Children's Hosptial
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 4-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 50 patient visits per month, St. Louis Children's Hospital

Teaching Title and Responsibilities

2009 - Pres	Lecturer, Markey Course-Diabetes Module
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington
	University School of Medicine

University, School of Medicine and Hospital Appointments and Committees

University

2012 - 2020 Disorders of Sexual Development Multidisciplinary Care Program

School of Medicine

2013 - 2020	Molecular Cell Biology Graduate Student Admissions Committee
2014 - Pres	Research Consultant, ICTS Research Forum - Child Health
2020 - Pres	WU ICTS Clinical and Translational Research Funding Program (CTRFP) Review
	Committee

Department/Division

2008 - 2016	Director, Pediatric Endocrinology & Diabetes Fellowship Program
2014 - 2017	Director, Pediatric Diabetes Research Consortium

Hospital

2000 - Pres Attending Physician, St. Louis Children's Hospital

Medical Licensure and Certifications

1997 - Pres	Board Certified in General Pediatrics
2000 - Pres	MO State License #2000155004
2001 - Pres	Board Certified in Pediatric Endocrinology & Metabolism

Honors and Awards

1987	National Institute of Chemists Research and Recognition Award
1987	Phi Beta Kappa
1987	Phi Lambda Upsilon (Honorary Chemical Society)
1988	American Heart Association Predoctoral Fellowship Award
1994	Alpha Omega Alpha
1994	Armond J. Quick Award for Excellence in Biochemistry
1994	NIDDK/Diabetes Branch Most Outstanding Resident
1998	Pfizer Postdoctoral Fellowship Award
2002	Scholar, Child Health Research Center of Excellence in Developmental Biology at Washington University
2013	Julio V Santiago, M.D. Scholar in Pediatrics
2017	Redemptor Hominis Award for Outstanding Contributions to the Study of Bioethics
2018	Eli Lilly Outstanding Contribution to Drug Discovery: Emerging Biology Award
2018	Scholar-Innovator Award, Harrington Discovery Institute

Editorial Responsibilities

Editorial Ad Hoc Reviews

AIDS

AIDS Research and Human Retroviruses

American Journal of Pathology

American Journal of Physiology

British Journal of Pharmacology

Circulation Research

Clinical Pharmacology & Therapeutics

Comparative Biochemistry and Physiology

Diabetes

Experimental Biology and Medicine

Future Virology

Journal of Antimicrobial Chemotherapy

Journal of Clinical Endocrinology & Metabolism

Journal of Molecular and Cellular Cardiology

Obesity Research

2000 - Pres Journal of Biological Chemistry

2013 - Pres PlosOne

2016 - Pres Scientific Reports

2018 - Pres Nutrients

Editorial Boards

2014 Endocrinology and Metabolism Clinics of North America

Community Service Contributions

Professional Societies and Organizations

1992 - 2004	American Medical Association
1994 - 2005	American Academy of Pediatrics
1995 - 2014	American Association for the Advancement of Science
1998 - Pres	American Diabetes Association
1998 - Pres	Endocrine Society
1999 - Pres	Pediatric Endocrine Society
2004 - 2007	American Chemical Society
2004 - 2018	American Society for Biochemistry and Molecular Biology
2004 - 2020	Society for Pediatric Research
2005 - 2020	Full Fellow of the American Academy of Pediatrics
2013 - Pres	International Society for Pediatric and Adolescent Diabetes
2017 - Pres	Catholic Medical Association
2018 - Pres	American College of Pediatricians
2019 - Pres	Society of Catholic Scientists

Major Invited Professorships and Lectures

2002	Pediatric Grand Rounds, St. Louis Children's Hospital, St Louis, MO
2004	National Disease Research Interchange, Human Islet Cell Research Conference, Philadelphia, PA
2004	NIDA-NIH Sponsored National Meeting on Hormones, Drug Abuse and Infections, Bethesda, MD
2005	Endocrine Grand Rounds, University of Indiana, Indianapolis, IN
2005	The Collaborative Institute of Virology, Complications Committee Meeting, Boston, MA
2006	Metabolic Syndrome Advisory Board Meeting, Bristol-Meyers Squibb, Pennington, NJ
2007	American Heart Association and American Academy of HIV Medicine State of the Science Conference: Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS, Chicago, IL
2007	Minority Access to Research Careers Seminar, University of Arizona, Tucson, AZ
2007	MSTP Annual Visiting Alumnus Lecture, Medical College of Wisconsin , Milwaukee, WI
2007	Pediatric Grand Rounds, St Louis Children's Hospital, St Louis, MO
2008	Division of Endocrinology, Diabetes and Nutrition Grand Rounds, Boston University, Boston, MA
2009	Pediatric Grand Rounds, St Louis Children's Hospital, St. Louis, MO
2010	American Diabetes Association Scientific Sessions, Symposium Lecture Orlando, FL
2010	School of Biological Sciences Conference Series, University of Missouri Kansas City, Kansas City, MO
2011	Life Cycle Management Advisory Board Meeting, Bristol-Myers Squibb,, Chicago, IL
2013	Pediatric Grand Rounds, St Louis Children's Hospital, ST LOUIS, MO
2013	Clinical Practice Update Lecture, St Louis Children's Hospital, St Louis, MO
2014	Pediatric Academic Societies Meeting, Vancouver, Canada

American Diabetes Association 74th Scientific Sessions, , San Francisco, CA
Division of Pediatric Endocrinology Metabolism Rounds, University of Michigan, Ann Arbor, MI
Catholic Medical Association National Conference, Denver, CO
Obstetrics, Gynecology & Women's Health Grand Rounds, Saint Louis University, St. Louis, MO
Medical Grand Rounds, Sindicato Médico del Uruguay, Montevideo, Uraquay
Internal Medicine Grand Rounds, Texas Tech , Lubbock, TX
Veritas Center for Ethics in Public Life Conference, Franciscan University, Steubenville, OH
MaterCare International Conference, Rome, Italy
Child Health Policy Forum, Notre Dame University, South Bend , IN
Obstetrics & Gynecology Grand Rounds, University of Tennessee, Knoxville , TN

Consulting Relationships and Board Memberships

1996 - 2012	Consultant, Bristol Myers Squibb
1997 - 2012	Consultant, Gilead Sciences

Research Support

Completed Governmental Support

2001 - 2006	K-08 A149747, NIH Mechanism of GLUT4 Inhibition by HIV Protease Inhibitors Role: Principal Investigator
2007 - 2012	R01 Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: \$800,000.00
2009 - 2011	R01 Student Supp Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: \$25,128.00
2009 - 2014	R01 Direct Effects of Antiretroviral Therapy on Cardiac Energy Homeostasis Role: Principal Investigator Total cost: \$1,250,000.00
2017 - 2019	R-21 1R21AI130584, National Institutes of Health SELECTIVE INHIBITION OF THE P. FALCIPARUM GLUCOSE TRANSPORTER PFHT Role: Principal Investigator Total cost: \$228,750.00

Completed Non-Governmental Support

Novel HIV Protease Inhibitors and GLUT4

Role: Principal Investigator

2008 - 2011 II

Insulin Resistance and Myocardial Glucose Metabolism in Pediatric Heart Failure

Role: Co-Investigator

PI: Hruz

Total cost: \$249,999.00

2009 - 2012 Research Program

Regulation of GLUT4 Intrinsic Activity

Role: Principal Investigator Total cost: \$268,262.00

2010 - 2011 Protective Effect of Saxagliptin on a Progressive Deterioration of Cardiovascular Function

Role: Principal Investigator

2012 - 2015 II

Solution-State NMR Structure and Dynamics of Facilitative Glucose Transport Proteins

Role: Principal Investigator Total cost: \$375,000.00

2017 - 2020 Prevention And Treatment Of Hepatic Steatosis Through Selective Targeting Of GLUT8

Role: Co-Principal Investigator

PI: DeBosch

Total cost: \$450,000.00

2018 - 2021 LEAP Innovator Challenge

Novel Treatment of Fatty Liver Disease

Role: Principal Investigator Total cost: \$68,500.00

Current Non-Governmental Support

2017 - 2021 Matching Micro Grant

Novel Treatment of Fatty Liver Disease (CDD/LEAP)

Role: Principal Investigator Total cost: \$68,500.00

2019 - 2021 Scholar-Innovator Award HDI2019-SI-4555, Harrington Foundation

Novel Treatment of Non-Alcoholic Fatty Liver Disease

Role: Principal Investigator Total cost: \$379,000.00

Pending Non-Governmental Support

Novel HIV Protease Inhibitors and GLUT4

Role: Principal Investigator

Trainee/Mentee/Sponsorship Record

Current Trainees

2019 Ava Suda, Other, Pre-med

Past Trainees

2002 - 2002 Nishant Raj- Undergraduate Student, Other

Study area: Researcher

2002 - 2010	Joseph Koster, PhD, Postdoctoral Fellow Study area: Researcher
2003 - 2004	Johann Hertel, Medical Student Study area: Research Present position: Assistant Professor, University of North Carolina, Chapel Hill, NC
2003 - 2003	John Paul Shen, Medical Student Study area: Research
2004 - 2005	Carl Cassel- High School Student, Other Study area: Research
2004 - 2004	Christopher Hawkins- Undergraduate Student, Other Study area: Researcher
2004 - 2004	Kaiming Wu- High School Student, Other Study area: Research
2005 - 2005	Helena Johnson, Graduate Student
2005 - 2005	Jeremy Etzkorn, Medical Student Study area: Researcher
2005 - 2005	Dominic Doran, DSc, Postdoctoral Fellow Study area: HIV Protease Inhibitor Effects on Exercize Tolerance
2006 - 2006	Ramon Jin, Graduate Student Study area: Research
2006 - 2006	Taekyung Kim, Graduate Student Study area: Research
2007 - 2007	Jan Freiss- Undergraduate Student, Other Study area: Researcher
2007 - 2008	Kai-Chien Yang, Graduate Student Study area: Research Present position: Postdoctoral Research Associate, University of Chicago
2007 - 2007	Paul Buske, Graduate Student Study area: Research
2007 - 2007	Randy Colvin, Medical Student Study area: Researcher
2008 - 2011	Arpita Vyas, MD, Clinical Fellow Study area: Research Present position: Assistant Professor, Michigan State University, Lansing MI
2008 - 2009	Candace Reno, Graduate Student Study area: Research Present position: Research Associate, University of Utah
2008 - 2012	Dennis Woo- Undergraduate Student, Other Study area: Researcher Present position: MSTP Student, USC, Los Angeles CA
2008 - 2008	Temitope Aiyejorun, Graduate Student Study area: Research
2009 - 2009	Anne-Sophie Stolle- Undergraduate Student, Other Study area: Research
2009 - 2009	Matthew Hruz- High School Student, Other Study area: Research Present position: Computer Programmer, Consumer Affairs, Tulsa OK

2009 - 2009	Stephanie Scherer, Graduate Student
	Study area: Research
2010 - 2014	Lauren Flessner, PhD, Postdoctoral Fellow
	Present position: Instructor, Syracuse University
2010 - 2010	Constance Haufe- Undergraduate Student, Other
	Study area: Researcher
2010 - 2011	Corinna Wilde- Undergraduate Student, Other
	Study area: Researcher
2010 - 2010	Samuel Lite- High School Student, Other
	Study area: Research
2011 - 2016	Thomas Kraft, Graduate Student
	Study area: Glucose transporter structure/function
	Present position: Postdoctoral Fellow, Roche, Penzberg, Germany
2011 - 2011	Amanda Koenig- High School Student, Other
	Study area: Research
2011 - 2012	Lisa Becker- Undergraduate Student, Other
2011 - 2011	Melissa Al-Jaoude- High School Students, Other
2014 - 2014	David Hannibal, Clinical Research Trainee

Bibliography

Journal Articles

- 1. Hruz PW, Narasimhan C, Miziorko HM. 3-Hydroxy-3-methylglutaryl coenzyme A lyase: affinity labeling of the Pseudomonas mevalonii enzyme and assignment of cysteine-237 to the active site. *Biochemistry*. 1992;31(29):6842-7. PMID:<u>1637819</u>
- 2. Hruz PW, Miziorko HM. Avian 3-hydroxy-3-methylglutaryl-CoA lyase: sensitivity of enzyme activity to thiol/disulfide exchange and identification of proximal reactive cysteines. *Protein Sci.* 1992;1(9):1144-53. doi:10.1002/pro.5560010908 PMCID:PMC2142181 PMID:1304393
- 3. Mitchell GA, Robert MF, Hruz PW, Wang S, Fontaine G, Behnke CE, Mende-Mueller LM, Schappert K, Lee C, Gibson KM, Miziorko HM. 3-Hydroxy-3-methylglutaryl coenzyme A lyase (HL). Cloning of human and chicken liver HL cDNAs and characterization of a mutation causing human HL deficiency. *J Biol Chem.* 1993;268(6):4376-81. PMID:8440722
- 4. Hruz PW, Anderson VE, Miziorko HM. 3-Hydroxy-3-methylglutaryldithio-CoA: utility of an alternative substrate in elucidation of a role for HMG-CoA lyase's cation activator. *Biochim Biophys Acta*. 1993;1162(1-2):149-54. PMID:8095409
- 5. Roberts JR, Narasimhan C, Hruz PW, Mitchell GA, Miziorko HM. 3-Hydroxy-3-methylglutaryl-CoA lyase: expression and isolation of the recombinant human enzyme and investigation of a mechanism for regulation of enzyme activity. *J Biol Chem.* 1994;269(27):17841-6. PMID:8027038
- 6. Hruz PW, Mueckler MM. Cysteine-scanning mutagenesis of transmembrane segment 7 of the GLUT1 glucose transporter. *J Biol Chem.* 1999;274(51):36176-80. PMID:10593902
- Murata H, Hruz PW, Mueckler M. The mechanism of insulin resistance caused by HIV protease inhibitor therapy. *J Biol Chem.* 2000;275(27):20251 doi:10.1074/jbc.C000228200 PMID:10806189
- 8. Hruz PW, Mueckler MM. Cysteine-scanning mutagenesis of transmembrane segment 11 of the GLUT1 facilitative glucose transporter. *Biochemistry*. 2000;39(31):9367-72. PMID:10924131
- 9. Hruz PW, Mueckler MM. Structural analysis of the GLUT1 facilitative glucose transporter (review). *Mol Membr Biol*. 2001;18(3):183-93. PMID:<u>11681785</u>

- 10. Murata H, Hruz PW, Mueckler M. Investigating the cellular targets of HIV protease inhibitors: implications for metabolic disorders and improvements in drug therapy. *Curr Drug Targets Infect Disord*. 2002;2(1):1-8. PMID:12462148
- 11. Hruz PW, Murata H, Qiu H, Mueckler M. Indinavir induces acute and reversible peripheral insulin resistance in rats. *Diabetes*. 2002;51(4):937-42. PMID:<u>11916910</u>
- 12. Murata H, Hruz PW, Mueckler M. Indinavir inhibits the glucose transporter isoform Glut4 at physiologic concentrations. *AIDS*. 2002;16(6):859-63. PMID:11919487
- 13. Koster JC, Remedi MS, Qiu H, Nichols CG, Hruz PW. HIV protease inhibitors acutely impair glucose-stimulated insulin release. *Diabetes*. 2003;52(7):1695-700. PMCID:PMC1403824 PMID:12829635
- Liao Y, Shikapwashya ON, Shteyer E, Dieckgraefe BK, Hruz PW, Rudnick DA. Delayed hepatocellular mitotic progression and impaired liver regeneration in early growth response-1deficient mice. *J Biol Chem.* 2004;279(41):43107-16. doi:10.1074/jbc.M407969200 PMID:15265859
- 15. Shteyer E, Liao Y, Muglia LJ, Hruz PW, Rudnick DA. Disruption of hepatic adipogenesis is associated with impaired liver regeneration in mice. *Hepatology*. 2004;40(6):1322-32. doi:10.1002/hep.20462 PMID:15565660
- Hertel J, Struthers H, Horj CB, Hruz PW. A structural basis for the acute effects of HIV protease inhibitors on GLUT4 intrinsic activity. *J Biol Chem.* 2004;279(53):55147-52. doi:10.1074/jbc.M410826200 PMCID:PMC1403823 PMID:15496402
- 17. Yan Q, Hruz PW. Direct comparison of the acute in vivo effects of HIV protease inhibitors on peripheral glucose disposal. *J Acquir Immune Defic Syndr*. 2005;40(4):398-403. PMCID:PMC1360159 PMID:16280693
- 18. Hruz PW. Molecular Mechanisms for Altered Glucose Homeostasis in HIV Infection. *Am J Infect Dis.* 2006;2(3):187-192. PMCID:PMC1716153 PMID:17186064
- 19. Turmelle YP, Shikapwashya O, Tu S, Hruz PW, Yan Q, Rudnick DA. Rosiglitazone inhibits mouse liver regeneration. *FASEB J.* 2006;20(14):2609-11. doi:10.1096/fj.06-6511fje PMID:17077279
- 20. Hruz PW, Yan Q, Struthers H, Jay PY. HIV protease inhibitors that block GLUT4 precipitate acute, decompensated heart failure in a mouse model of dilated cardiomyopathy. *FASEB J*. 2008;22(7):2161-7. doi:10.1096/fj.07-102269 PMID:18256305
- 21. Hruz PW. HIV protease inhibitors and insulin resistance: lessons from in-vitro, rodent and healthy human volunteer models. *Curr Opin HIV AIDS*. 2008;3(6):660-5. doi:10.1097/COH.0b013e3283139134 PMCID:PMC2680222 PMID:19373039
- 22. Flint OP, Noor MA, Hruz PW, Hylemon PB, Yarasheski K, Kotler DP, Parker RA, Bellamine A. The role of protease inhibitors in the pathogenesis of HIV-associated lipodystrophy: cellular mechanisms and clinical implications. *Toxicol Pathol*. 2009;37(1):65-77. doi:10.1177/0192623308327119 PMCID:PMC3170409 PMID:19171928
- 23. Tu P, Bhasin S, Hruz PW, Herbst KL, Castellani LW, Hua N, Hamilton JA, Guo W. Genetic disruption of myostatin reduces the development of proatherogenic dyslipidemia and atherogenic lesions in Ldlr null mice. *Diabetes*. 2009;58(8):1739-48. doi:10.2337/db09-0349 PMCID:PMC2712781 PMID:19509018
- 24. Guo W, Wong S, Pudney J, Jasuja R, Hua N, Jiang L, Miller A, Hruz PW, Hamilton JA, Bhasin S. Acipimox, an inhibitor of lipolysis, attenuates atherogenesis in LDLR-null mice treated with HIV protease inhibitor ritonavir. *Arterioscler Thromb Vasc Biol.* 2009;29(12):2028-32. doi:10.1161/ATVBAHA.109.191304 PMCID:PMC2783673 PMID:19762785
- 25. Vyas AK, Koster JC, Tzekov A, Hruz PW. Effects of the HIV protease inhibitor ritonavir on GLUT4 knock-out mice. *J Biol Chem*. 2010;285(47):36395-400. doi:10.1074/jbc.M110.176321 PMCID:PMC2978568 PMID:20864532

- 26. Gazit V, Weymann A, Hartman E, Finck BN, Hruz PW, Tzekov A, Rudnick DA. Liver regeneration is impaired in lipodystrophic fatty liver dystrophy mice. *Hepatology*. 2010;52(6):2109-17. doi:10.1002/hep.23920 PMCID:PMC2991544 PMID:20967828
- 27. Hresko RC, Hruz PW. HIV protease inhibitors act as competitive inhibitors of the cytoplasmic glucose binding site of GLUTs with differing affinities for GLUT1 and GLUT4. *PLoS One*. 2011;6(9):e25237. doi:10.1371/journal.pone.0025237 PMCID:PMC3179492 PMID:21966466
- 28. Vyas AK, Yang KC, Woo D, Tzekov A, Kovacs A, Jay PY, Hruz PW. Exenatide improves glucose homeostasis and prolongs survival in a murine model of dilated cardiomyopathy. *PLoS One*. 2011;6(2):e17178. doi:10.1371/journal.pone.0017178 PMCID:PMC3040766 PMID:21359201
- 29. Hruz PW, Yan Q, Tsai L, Koster J, Xu L, Cihlar T, Callebaut C. GS-8374, a novel HIV protease inhibitor, does not alter glucose homeostasis in cultured adipocytes or in a healthy-rodent model system. *Antimicrob Agents Chemother*. 2011;55(4):1377-82. doi:10.1128/AAC.01184-10 PMCID:PMC3067185 PMID:21245443
- 30. Remedi MS, Agapova SE, Vyas AK, Hruz PW, Nichols CG. Acute sulfonylurea therapy at disease onset can cause permanent remission of KATP-induced diabetes. *Diabetes*. 2011;60(10):2515-22. doi:10.2337/db11-0538 PMCID:PMC3178299 PMID:21813803
- 31. Aerni-Flessner L, Abi-Jaoude M, Koenig A, Payne M, Hruz PW. GLUT4, GLUT1, and GLUT8 are the dominant GLUT transcripts expressed in the murine left ventricle. *Cardiovasc Diabetol*. 2012;11:63. doi:10.1186/1475-2840-11-63 PMCID:PMC3416696 PMID:22681646
- 32. Vyas AK, Aerni-Flessner LB, Payne MA, Kovacs A, Jay PY, Hruz PW. Saxagliptin Improves Glucose Tolerance but not Survival in a Murine Model of Dilated Cardiomyopathy. *Cardiovasc Endocrinol*. 2012;1(4):74-82. doi:10.1097/XCE.0b013e32835bfb24 PMCID:PMC3686315 PMID:23795310
- 33. Hresko RC, Kraft TE, Tzekov A, Wildman SA, Hruz PW. Isoform-selective inhibition of facilitative glucose transporters: elucidation of the molecular mechanism of HIV protease inhibitor binding. *J Biol Chem.* 2014;289(23):16100-16113. doi:10.1074/jbc.M113.528430 PMCID:PMC4047383 PMID:24706759
- 34. Mishra RK, Wei C, Hresko RC, Bajpai R, Heitmeier M, Matulis SM, Nooka AK, Rosen ST, Hruz PW, Schiltz GE, Shanmugam M. In Silico Modeling-based Identification of Glucose Transporter 4 (GLUT4)-selective Inhibitors for Cancer Therapy. *J Biol Chem.* 2015;290(23):14441-53. doi:10.1074/jbc.M114.628826 PMID:25847249
- 35. Kraft TE, Hresko RC, Hruz PW. Expression, purification, and functional characterization of the insulin-responsive facilitative glucose transporter GLUT4. *Protein Sci*. 2015. doi:10.1002/pro.2812 PMID:26402434
- 36. Kraft TE, Armstrong C, Heitmeier MR, Odom AR, Hruz PW. The Glucose Transporter PfHT1 Is an Antimalarial Target of the HIV Protease Inhibitor Lopinavir. *Antimicrob Agents Chemother*. 2015;59(10):6203-9. doi:10.1128/AAC.00899-15 PMCID:PMC4576095 PMID:26248369
- 37. DeBosch BJ, Heitmeier MR, Mayer AL, Higgins CB, Crowley JR, Kraft TE, Chi M, Newberry EP, Chen Z, Finck BN, Davidson NO, Yarasheski KE, Hruz PW, Moley KH. Trehalose inhibits solute carrier 2A (SLC2A) proteins to induce autophagy and prevent hepatic steatosis. *Sci Signal*. 2016;9(416):ra21. doi:10.1126/scisignal.aac5472 PMID:26905426
- 38. Hresko RC, Kraft TE, Quigley A, Carpenter EP, Hruz PW. Mammalian Glucose Transporter Activity is Dependent upon Anionic and Conical Phospholipids. *J Biol Chem*. 2016. doi:10.1074/jbc.M116.730168 PMID:27302065
- 39. Kraft TE, Heitmeier MR, Putanko M, Edwards RL, Ilagan MX, Payne MA, Autry JM, Thomas DD, Odom AR, Hruz PW. A Novel Fluorescence Resonance Energy Transfer-Based Screen in High-Throughput Format To Identify Inhibitors of Malarial and Human Glucose Transporters. *Antimicrob Agents Chemother*. 2016;60(12):7407-7414. PMCID: PMC5119023 PMID: 27736766

- Mayer AL, Higgins CB, Heitmeier MR, Kraft TE, Qian X, Crowley JR, Hyrc KL, Beatty WL, Yarasheski KE, Hruz PW, DeBosch BJ. SLC2A8 (GLUT8) is a mammalian trehalose transporter required for trehalose-induced autophagy. *Sci Rep*. 2016;6:38586. PMCID:PMC5138640 PMID:27922102
- 41. Edwards RL, Brothers RC, Wang X, Maron MI, Ziniel PD, Tsang PS, Kraft TE, Hruz PW, Williamson KC, Dowd CS, John ARO. MEPicides: potent antimalarial prodrugs targeting isoprenoid biosynthesis. *Sci Rep.* 2017;7(1):8400. PMCID: PMC5567135 PMID: 28827774
- 42. Wei C, Bajpai R, Sharma H, Heitmeier M, Jain AD, Matulis SM, Nooka AK, Mishra RK, Hruz PW, Schiltz GE, Shanmugam M. Development of GLUT4-selective antagonists for multiple myeloma therapy. *Eur J Med Chem.* 2017;139:573-586. PMCID: PMC5603412 PMID: 28837922
- 43. Wei C, Heitmeier M, Hruz PW, Shanmugam M. Evaluating the Efficacy of GLUT Inhibitors Using a Seahorse Extracellular Flux Analyzer. *Methods Mol Biol.* 2018;1713:69-75. PMID:29218518
- 44. Heitmeier MR, Payne MA, Weinheimer C, Kovacs A, Hresko RC, Jay PY, Hruz PW. Metabolic and Cardiac Adaptation to Chronic Pharmacologic Blockade of Facilitative Glucose Transport in Murine Dilated Cardiomyopathy and Myocardial Ischemia. *Sci Rep.* 2018;8(1):6475. PMID:29691457
- 45. Zhang Y, Higgins CB, Mayer AL, Mysorekar IU, Razani BB, Graham MJ, Hruz PW, DeBosch BJ. TFEB-dependent Induction of Thermogenesis by the Hepatocyte SLC2A Inhibitor Trehalose. *Autophagy*. 2018. PMID: 29996716
- 46. Emfinger CH, Yan Z, Welscher A, Hung P, McAllister W, Hruz PW, Nichols CG, Remedi MS. Contribution of systemic inflammation to permanence of KATP-induced neonatal diabetes in mice. *Am J Physiol Endocrinol Metab*. 2018;315(6):E1121-E1132. PMCID:PMC6336961 PMID:30226997
- 47. Heitmeier MR, Hresko RC, Edwards RL, Prinsen MJ, Ilagan MXG, Odom John AR, Hruz PW. Identification of druggable small molecule antagonists of the Plasmodium falciparum hexose transporter PfHT and assessment of ligand access to the glucose permeation pathway via FLAG-mediated protein engineering. *PLoS One*. 2019;14(5):e0216457. PMCID: PMC6508677 PMID: 31071153
- 48. Hruz PW. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q.* 2020;87(1):34-42. PMCID:PMC7016442 PMID:32431446
- 49. Zhang Y, Shaikh N, Ferey JL, Wankhade UD, Chintapalli SV, Higgins CB, Crowley JR, Heitmeier MR, Stothard AI, Mihi B, Good M, Higashiyama T, Swarts BM, Hruz PW, Shankar K, Tarr PI, DeBosch BJ. Lactotrehalose, an Analog of Trehalose, Increases Energy Metabolism Without Promoting Clostridioides difficile Infection in Mice. *Gastroenterology*. 2020;158(5):1402-1416.e2. PMCID: PMC7103499 PMID: 31838076
- 50. Malone WJ, Hruz PW, Mason JW, Beck S. Letter to the Editor from William J. Malone: "Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective". *J Clin Endocrinol Metab*. 2021. PMID: 33772300

Book Chapters

- 1. Henderson KE, Baranski TJ, Bickel PE, Clutter PE, Clutter WE, McGill JB. Endocrine Disorders in HIV/AIDS. In: *The Washington Manual Endocrinology Subspecialty Consult* Philadelphia, PA; 2008:321-328.
- 2. Paul W Hruz. Medical Approaches to Alleviating Gender Dysphoria In: Edward J Furton, eds. *Transgender Issues in Catholic Health Care* Philadelphia PA; 2021:1-42.

Invited Publications

- 1. Grunfeld C, Kotler DP, Arnett DK, Falutz JM, Haffner SM, Hruz P, Masur H, Meigs JB, Mulligan K, Reiss P, Samaras K, Working Group 1. Contribution of metabolic and anthropometric abnormalities to cardiovascular disease risk factors. *Circulation*. 2008;118(2):e20-8. PMCID: PMC3170411 PMID: 18566314
- 2. Hruz PW. HIV protease inhibitors and insulin resistance: lessons from in-vitro, rodent and healthy human volunteer models. *Curr Opin HIV AIDS*. 2008;3(6):660-5. PMCID: PMC2680222 PMID: 19373039
- 3. Hruz PW. Molecular mechanisms for insulin resistance in treated HIV-infection. *Best Pract Res Clin Endocrinol Metab*. 2011;25(3):459-68. PMCID: PMC3115529 PMID: 21663839
- 4. Hruz PW. HIV and endocrine disorders. *Endocrinol Metab Clin North Am.* 2014;43(3): xvii–xviii. PMID: <u>25169571</u>
- 5. Hruz PW. Commentary. Clin Chem. 2015;61(12):1444. PMID: 26614228
- 6. Hruz PW, Mayer LS, and McHugh PR. Growing Pains: Problems with Pubertal Suppression in Treating Gender Dysphoria *The New Atlantis*. 2017;52:3-36.
- 7. Hruz, PW. The Use of Cross-Sex Steroids in Treating Gender Dysphoria *Natl Cathol Bioeth Q*. 2018;17(4):1-11.
- 8. Hruz, PW. Experimental Approaches to Alleviating Gender Dysphoria in Children *Nat Cathol Bioeth Q.* 2019;19(1):89-104.

Clinician Educator Portfolio

CLINICAL CONTRIBUTIONS

Summaries of ongoing clinical activities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per yr, St. Louis Children's Hosptial
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 4-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 50 patient visits per month, St. Louis Children's Hospital

EDUCATIONAL CONTRIBUTIONS

Direct teaching

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2009 - Pres	Lecturer, Markey Course-Diabetes Module
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington University School of Medicine

Clinical

2000 - Pres Lecturer, Medical Student Growth Lecture (Women and Children's Health Rotation): Variable

2000 - Pres 2009 - Pres 2016 - Pres	Lecturer, Pediatric Endocrinology Journal Club: Presentations yearly Facilitator, Medical Student Endocrinology and Metabolism Course, Small group Facilitator, Medical Student Endocrinology and Metabolism Course, Small group
<u>Other</u>	
	Facilitator, Cell Biology Graduate Student Journal Club, 4 hour/year
	Facilitator, Discussion: Pituitary, Growth & Gonadal Cases, 2 hours/year
2000 - Pres	Lecturer, Metabolism Clinical Rounds/Research Seminar: Presentations twice yearly
2009 - Pres	Facilitator, Biology 5011- Ethics and Research Science, 6 hours/year
2016 - Pres	Lecturer, Cell Signaling Course, Diabetes module, 3 hours/year